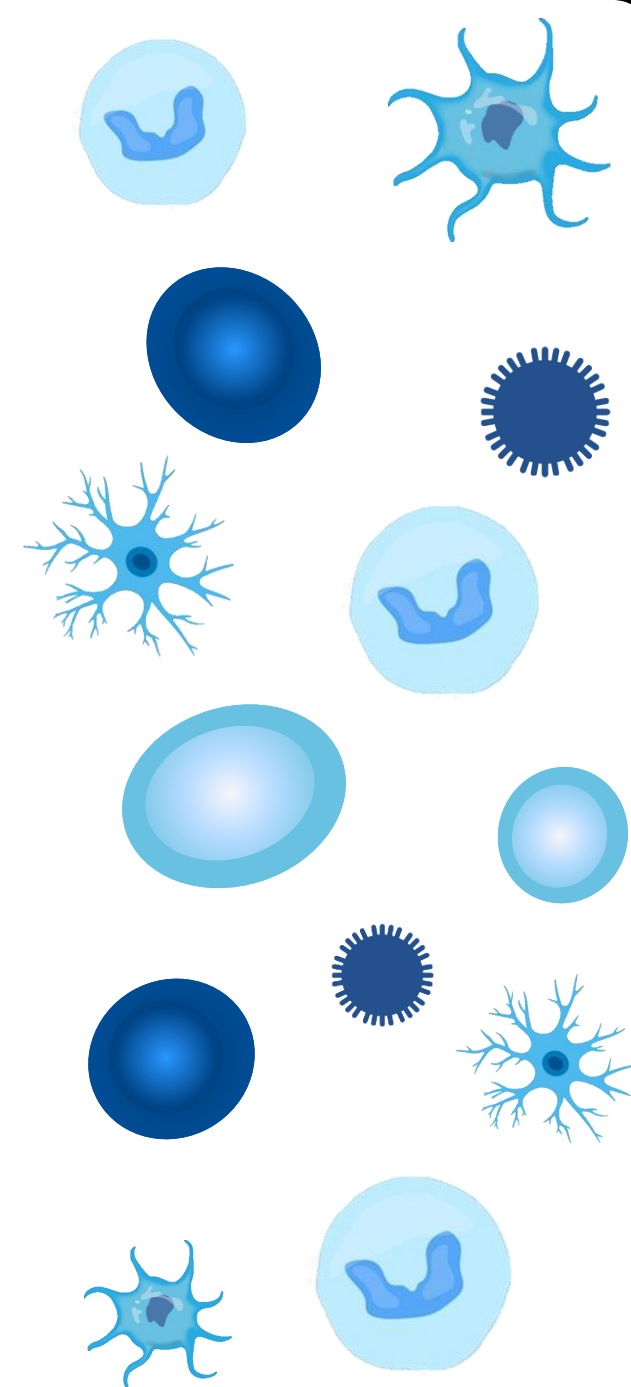


MaaT Pharma

# Boosting Survival Through Innovative Immune Modulation

February 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

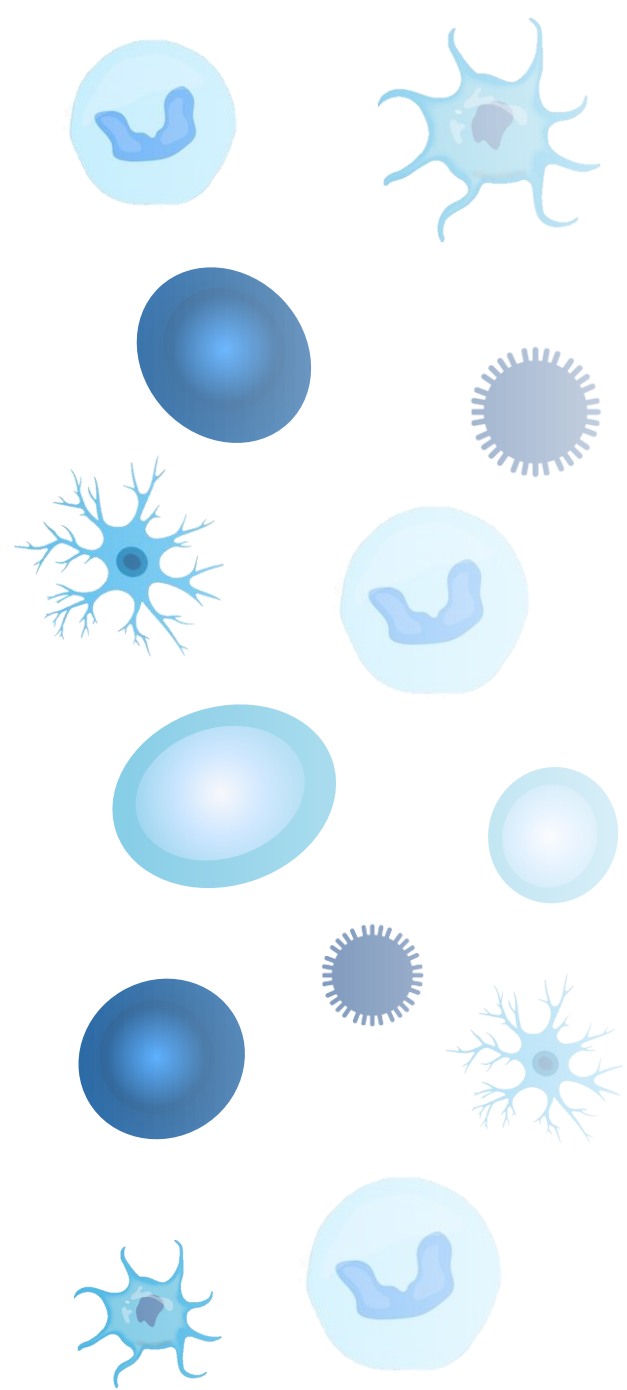
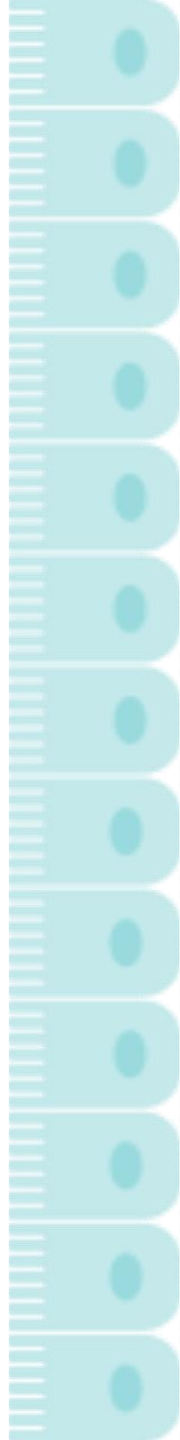
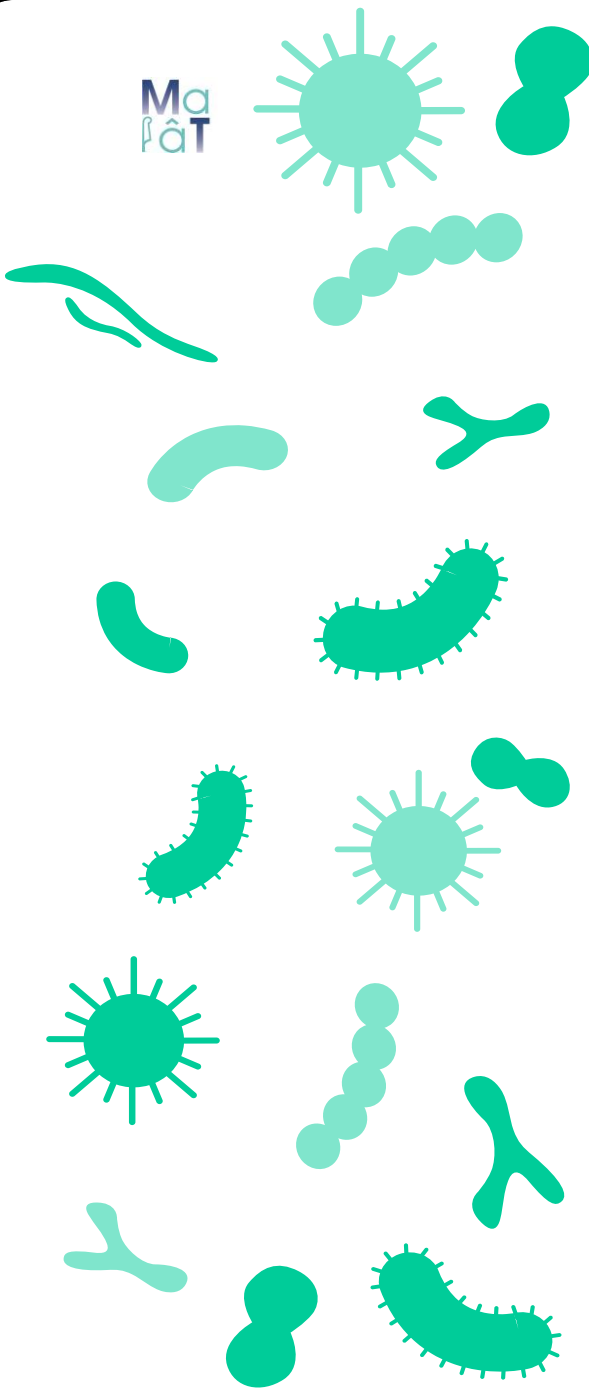


**Jonathan Chriqui,  
PharmD**

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 mid-2025**, earlier than initially planned



### 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

\*IRC reviewed

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

# Correcting Dysbiosis: a New Pillar in Oncology

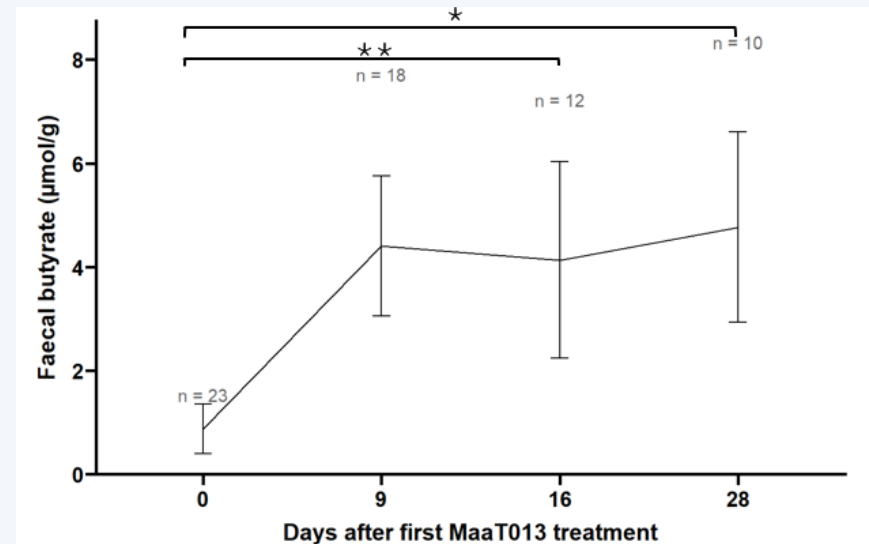
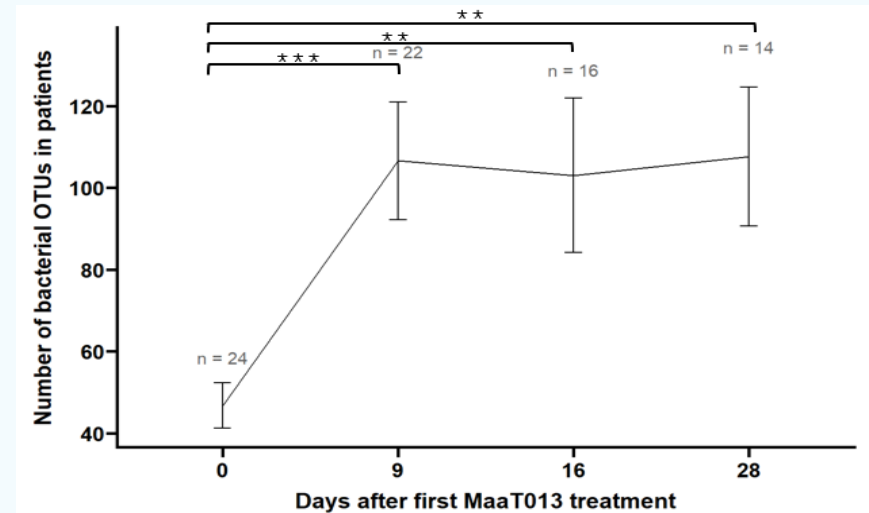
## Dysbiosis and disease

- 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

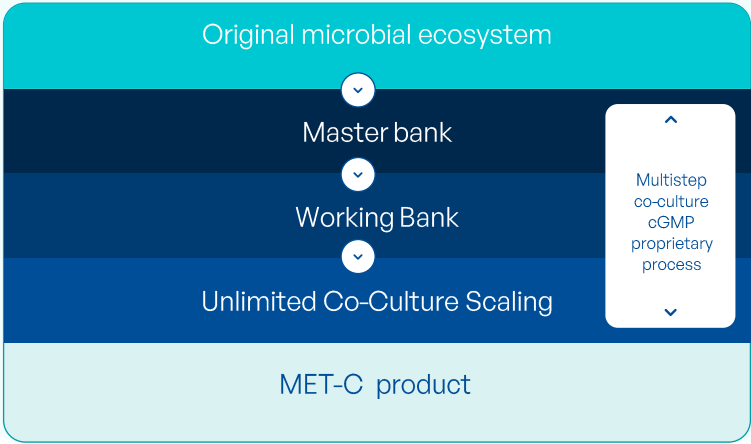


MaaT033

Pooled microbiota

→ Maximized richness

→ Standardized (450 OTU ± 3%)



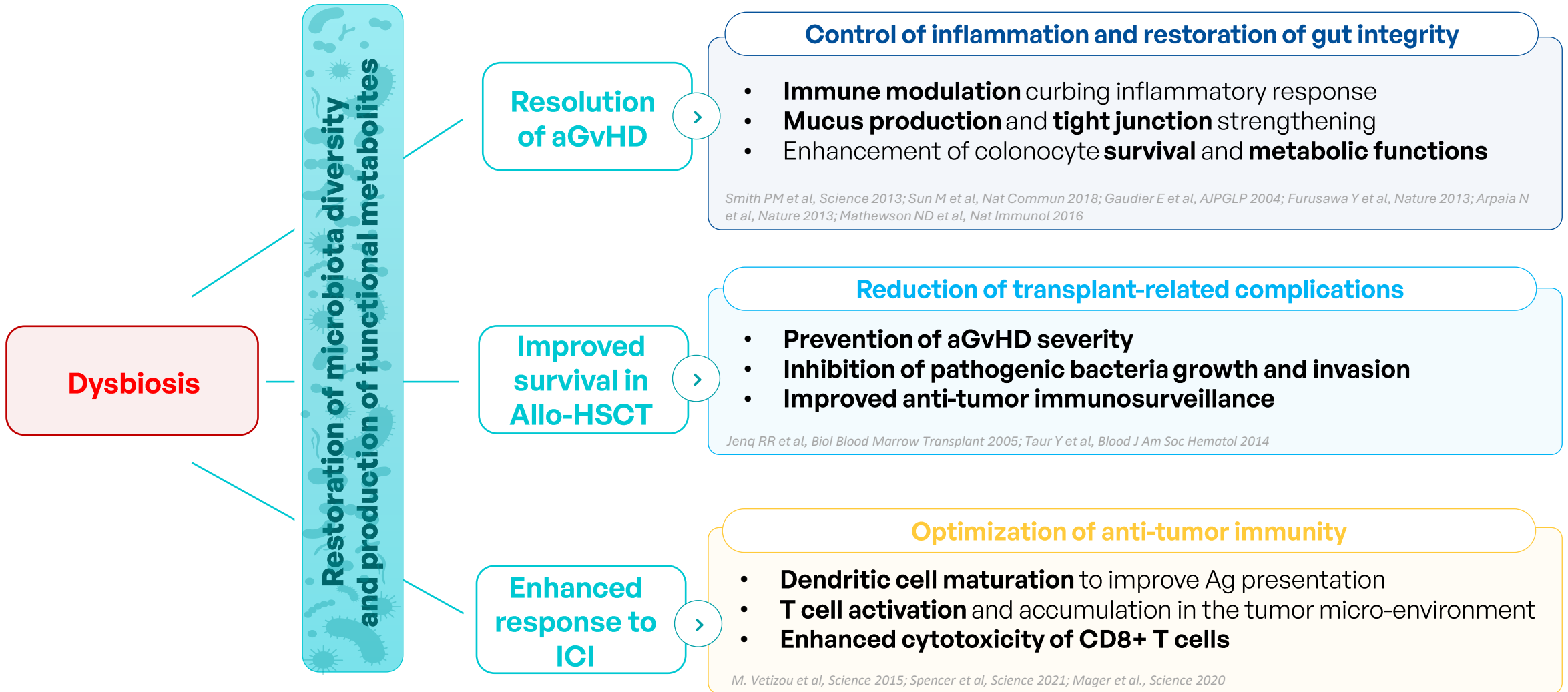
A Premier Portfolio of Full Native and Co-cultured Microbiome Ecosystem Therapies™ Produced Internally at the Largest European Production Facility Designed for Easy Scalability to Meet Demand

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

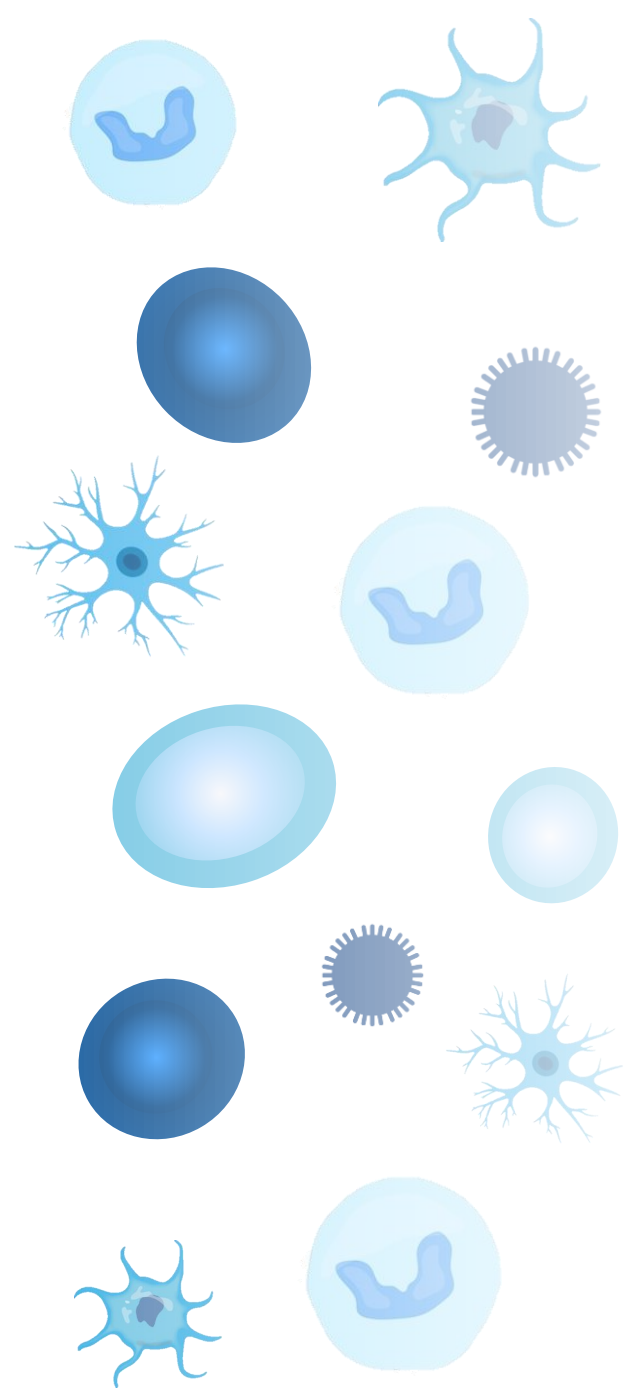
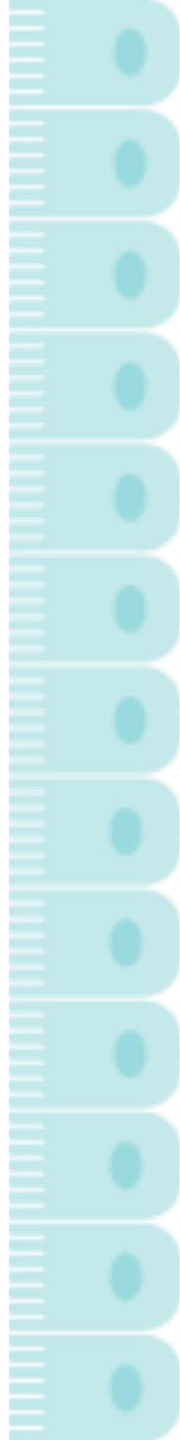
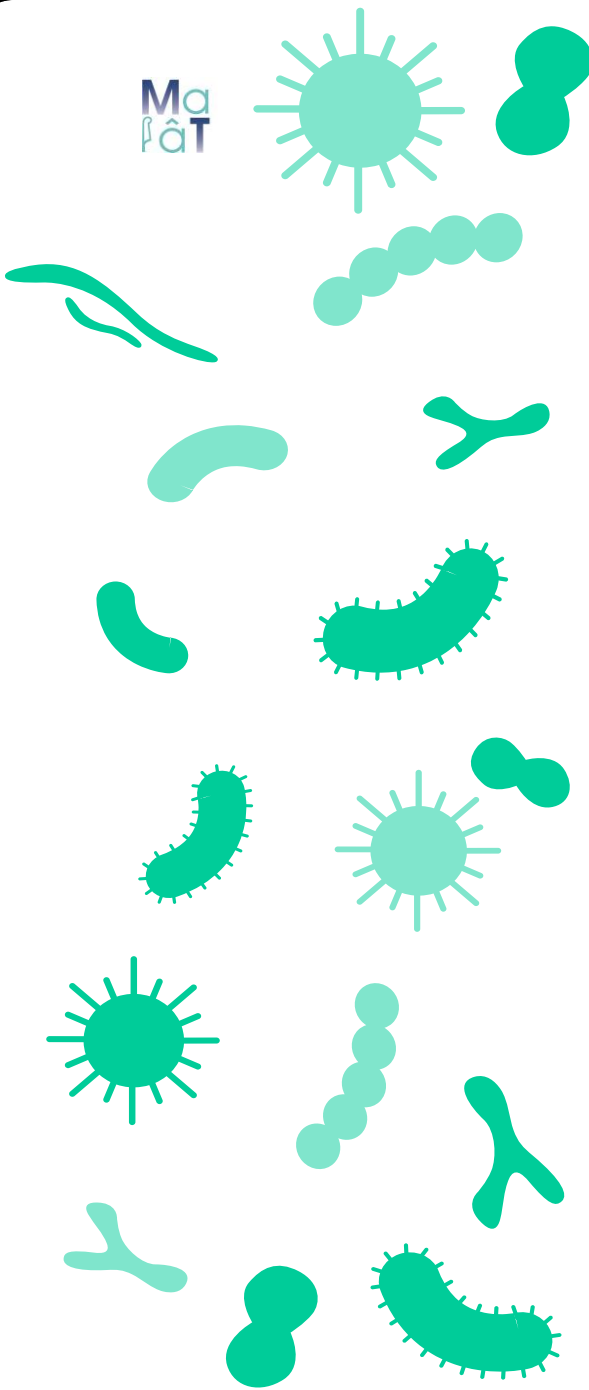
| Program                                                                                                                                                                                          | Indication                  | Market potential                                                         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

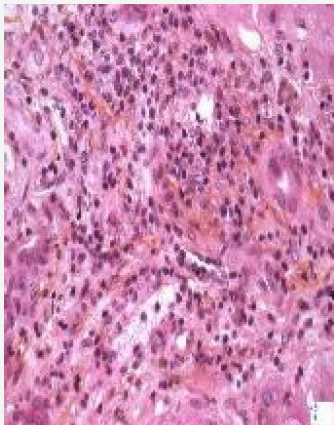
Common clinical manifestations typically involve the gastrointestinal tract, the skin and the liver

## 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%

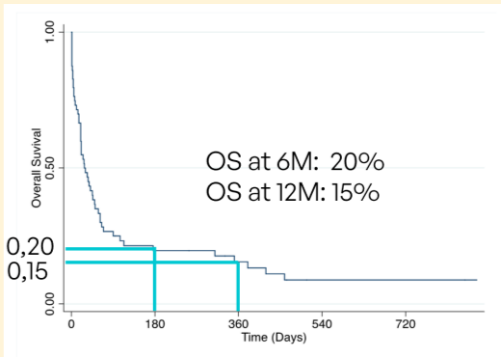
of aGvHD patients **eligible** for subsequent or alternative treatment



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>

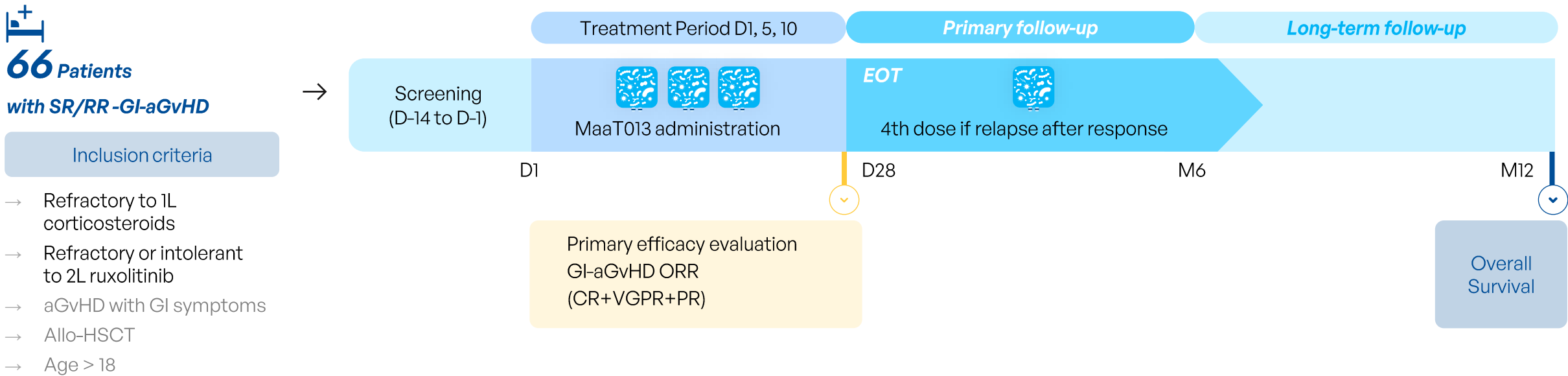
<sup>1</sup>Abedin et al., Br J Hematol 2021, <sup>2</sup>Peled et al., NEJM 2020; <sup>3</sup>Malard et al., ASH 2024

ARES: a Pivotal Phase 3 Trial Exploring MaaT013 in 3<sup>rd</sup>-Line aGvHD Following Steroid and Ruxolitinib Failure

ARES

→

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





## 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%)<br>Female: 31 (47%)                                                        |
| Steroid status n (%)                 | Steroid-refractory: 57 (86%)<br>Steroid-dependent: 9 (14%)                                |
| Ruxolitinib status n (%)             | <b>ruxolitinib refractory: 66 (100%)</b><br>ruxolitinib intolerant: 0                     |
| aGvHD grading (MAGIC*)               | Grade I: 0<br>Grade II: 6 (9%)<br><b>Grade III: 38 (58%)</b><br><b>Grade IV: 22 (33%)</b> |

\*MAGIC : Mount Sinai Acute GVHD International Consortium



Patients with severe aGvHD

**91% are Grade III-IV**



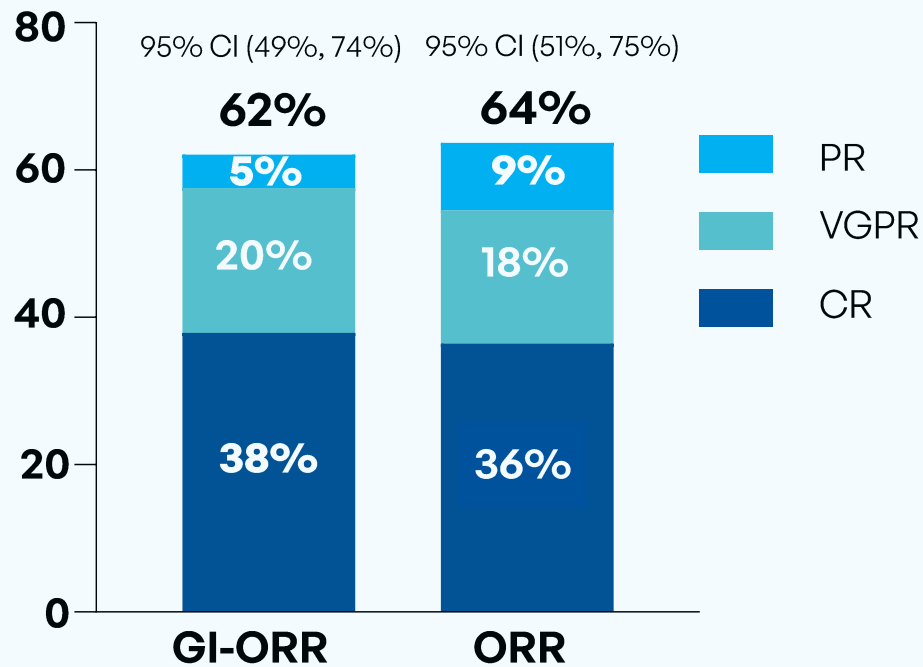
**100% are ruxolitinib refractory**



# 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.”

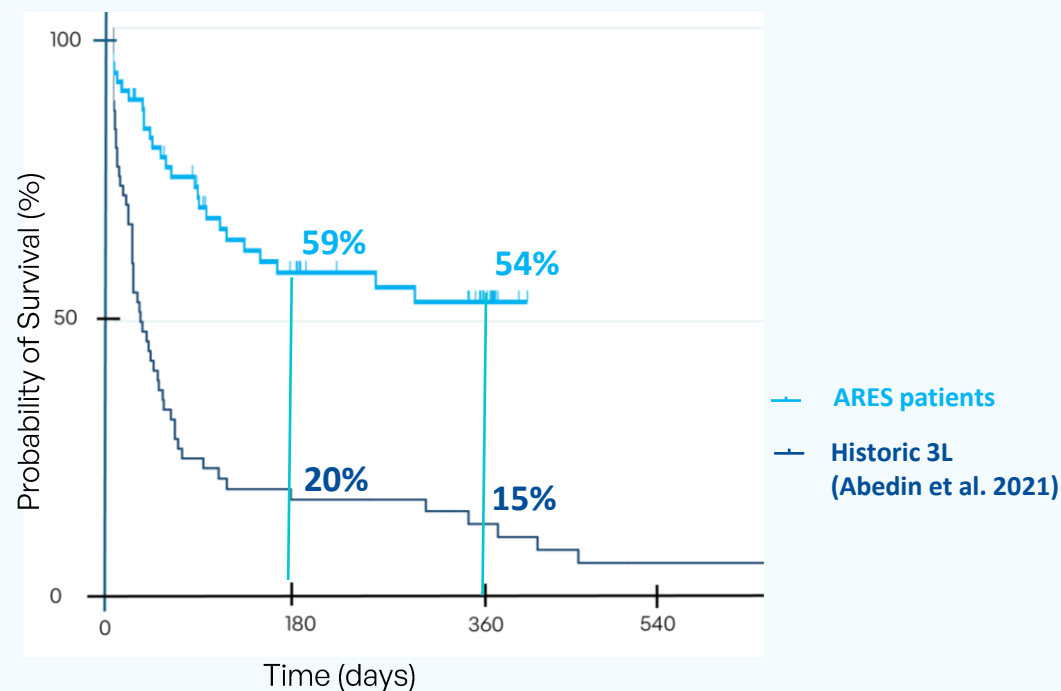
Prof. Malard, MD, hematology professor at Saint-Antoine Hospital and Sorbonne University, lead investigator for the Phase 3 ARES trial



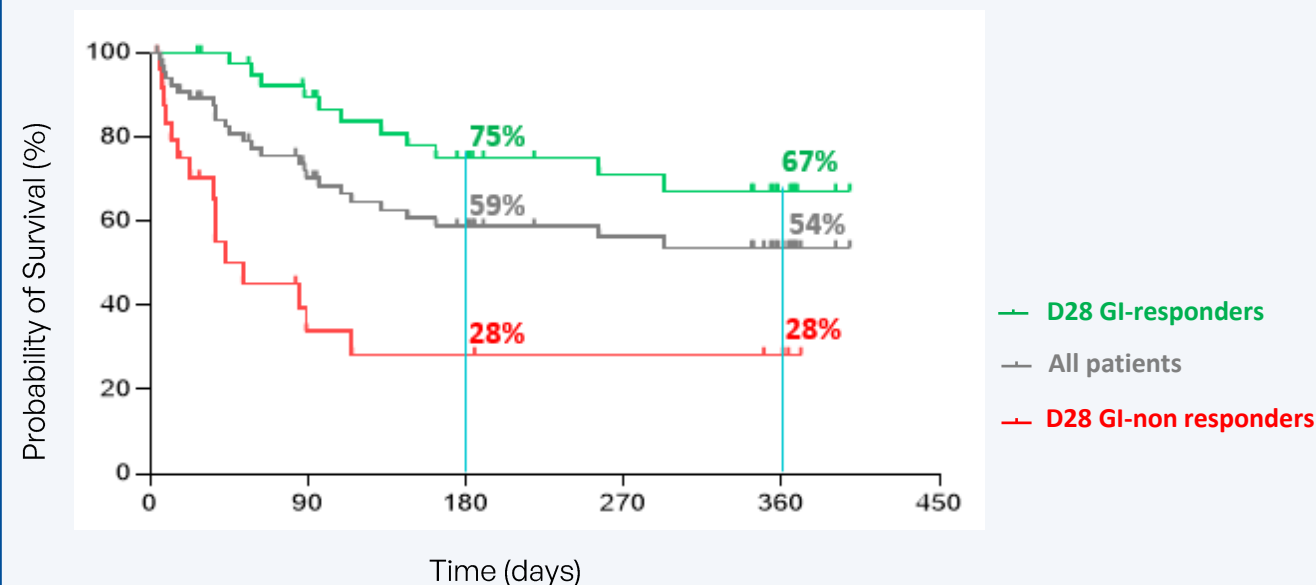
The study met its primary endpoint with a significant gastrointestinal **overall response rate (p < 0.0001)**

# 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

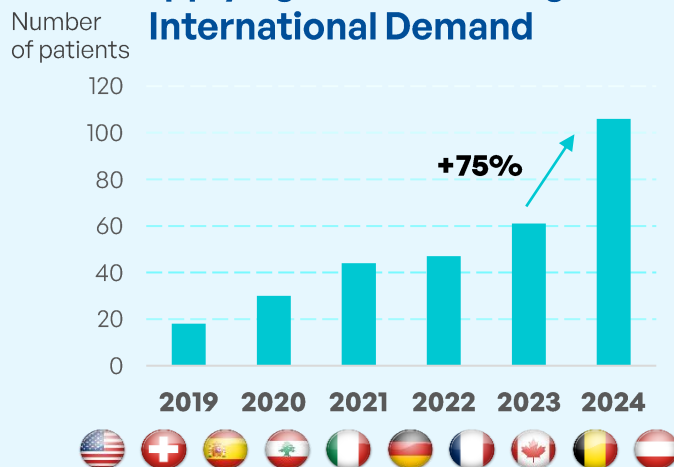
1

## 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%)**



# Clear Regulatory Path for MaaT013 in Third Line Refractory aGvHD

## In Europe



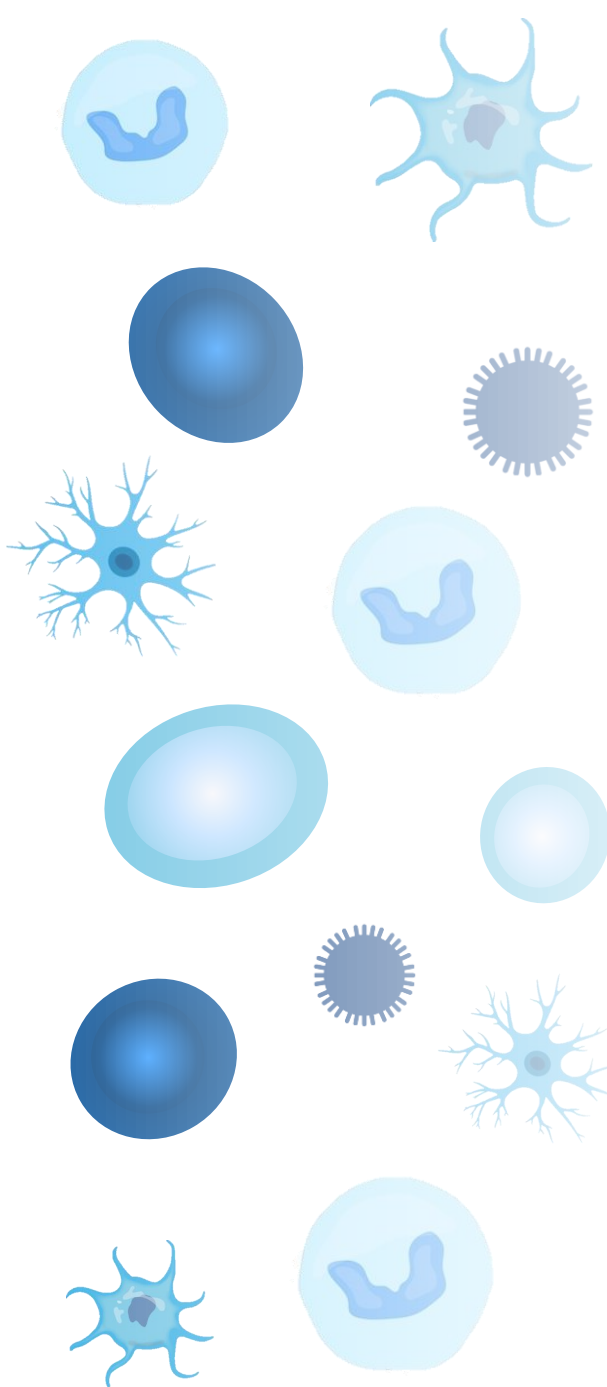
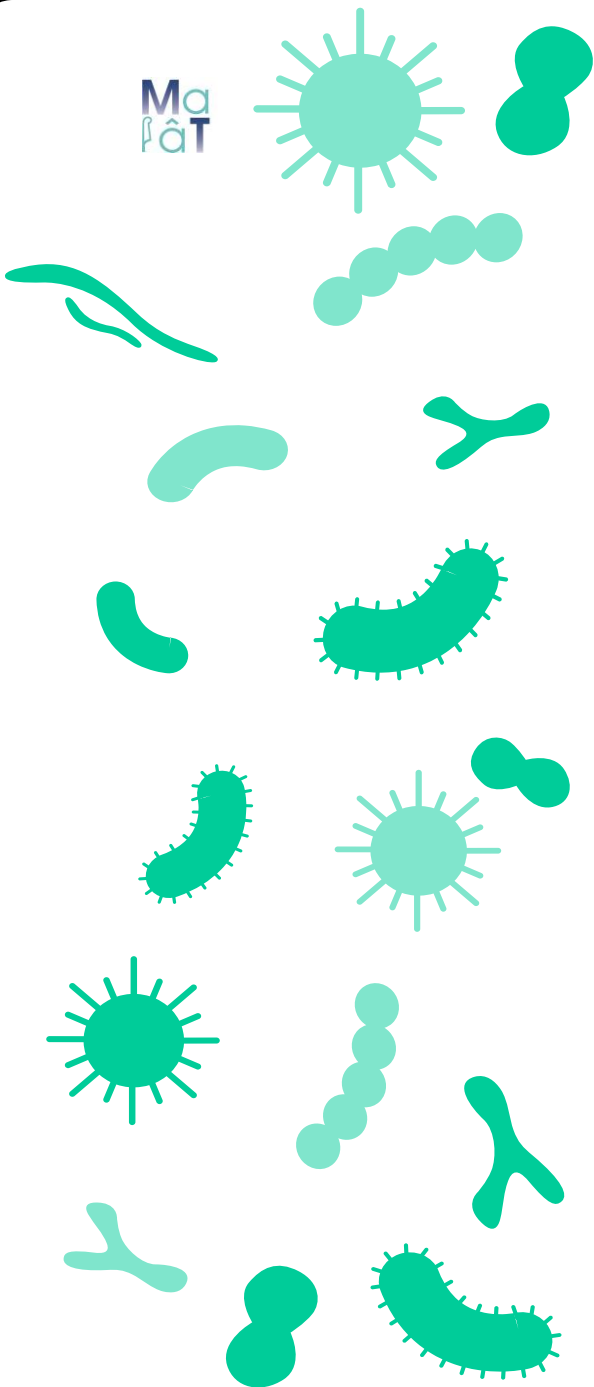
- Eligibility of MaaT013 for the **centralized procedure confirmed by EMA** (Medicinal product status) and rapporteurs and co-rapporteurs appointed
- **Target filing of the EMA Marketing Authorization Application** for MaaT013 **mid-2025** (6mths in advance vs previous plan)
- **Submission based on validated 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

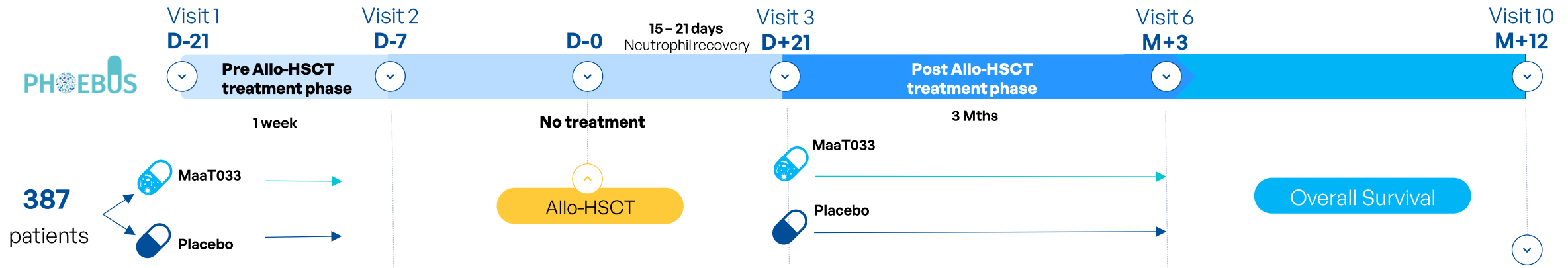


# Phoebus: MaaT033 Phase 2b RCT

## Potential Adjunctive Treatment for Patients Receiving Allo-HSCT



Design presented at EBMT, SOHO 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

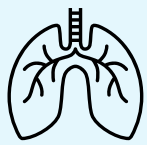


~ 11k patients per year

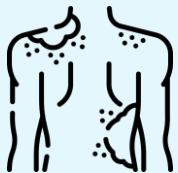
# Unlocking the Potential of Checkpoint Inhibitors: How Full-Ecosystem Gut Microbiome Overcomes Primary Resistance

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

## 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

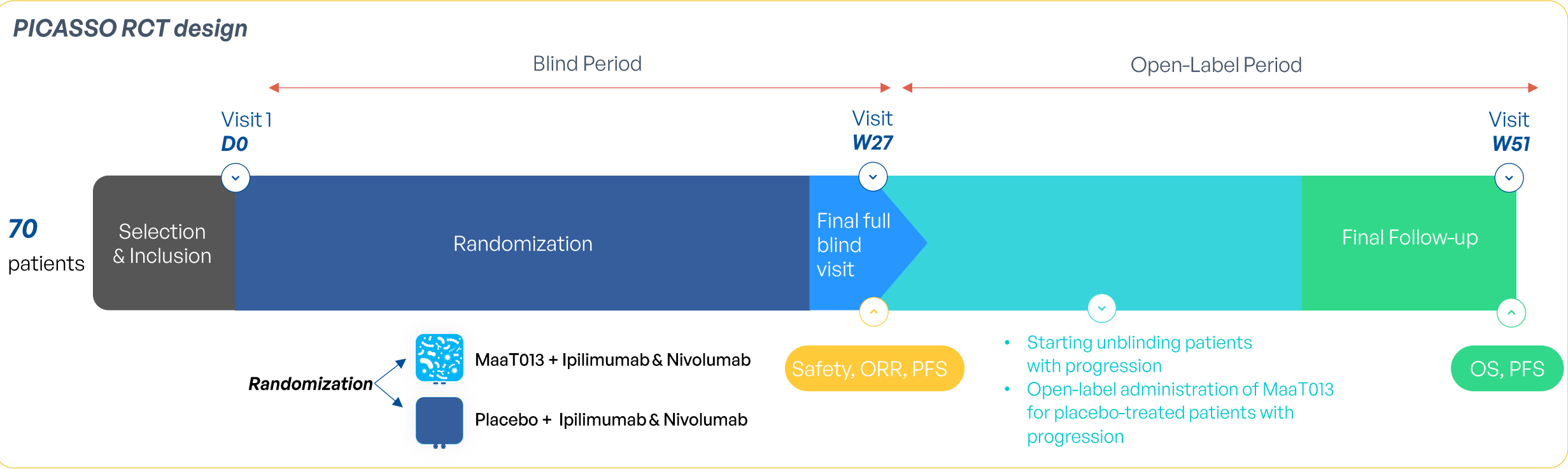
Phase 2a PICASSO trial, [fully recruited](#)

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

→ **Data expected 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





# 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

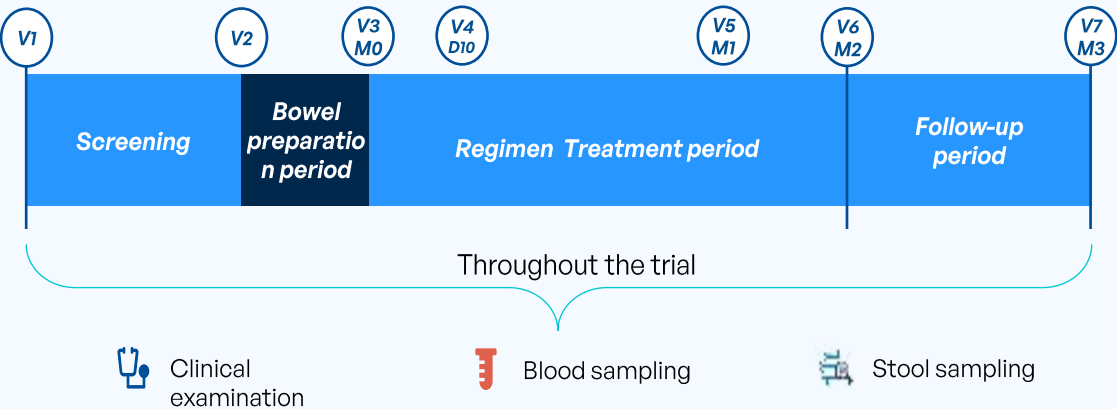
## Rationale for Exploratory Utilization of MaaT033 in ALS

- 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)



Study developed with:



In collaboration with:

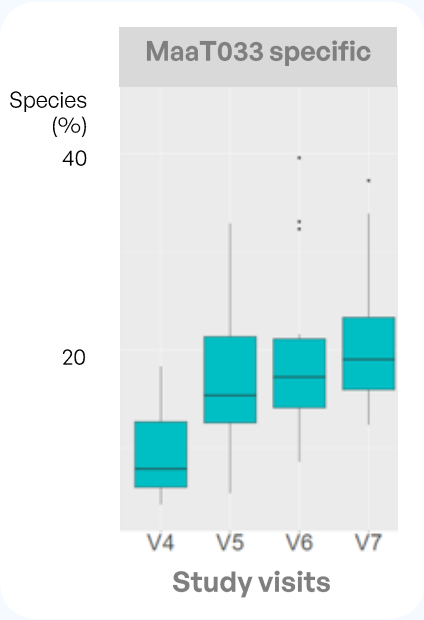


→ **Key study endpoints:** safety and tolerability of MaaT033 (**Primary**) | gut microbiota composition evolution | marker showing potential impact on disease progression

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

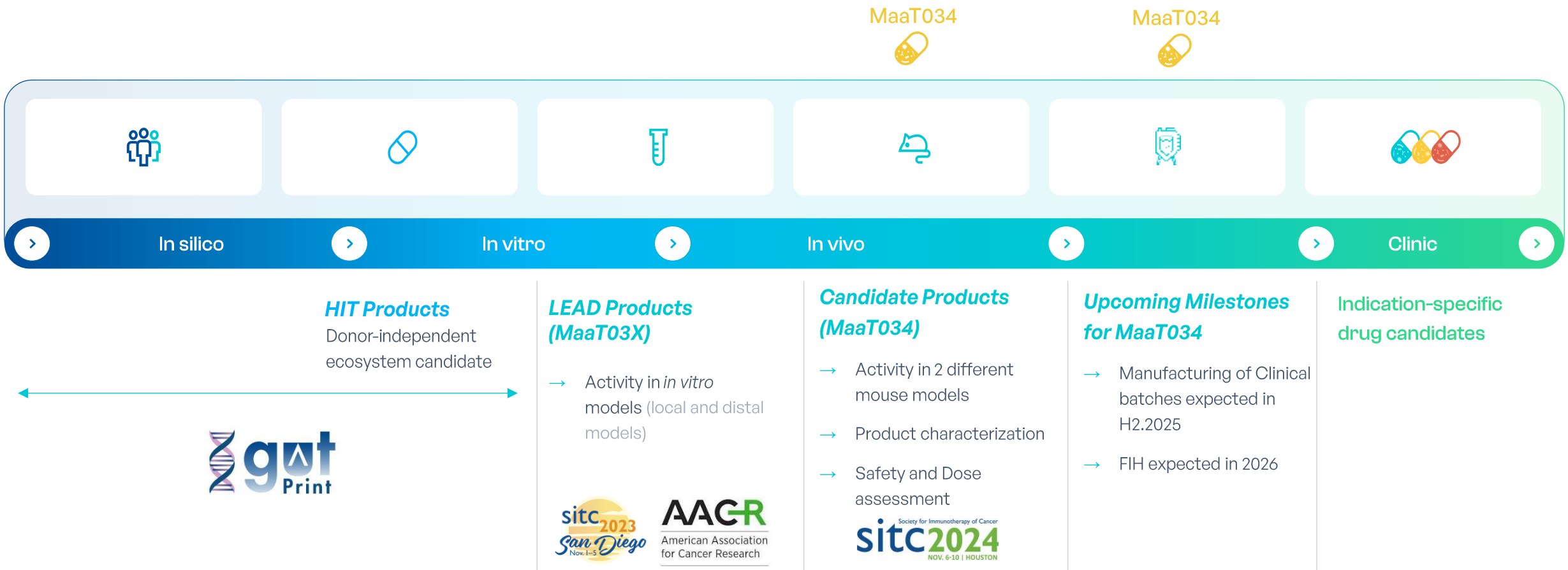
- MaaT033 found to be safe and well tolerated
- DSMB supports proceeding to Phase 2
- Successful engraftment characterized by the increasing MaaT033 species overtime

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

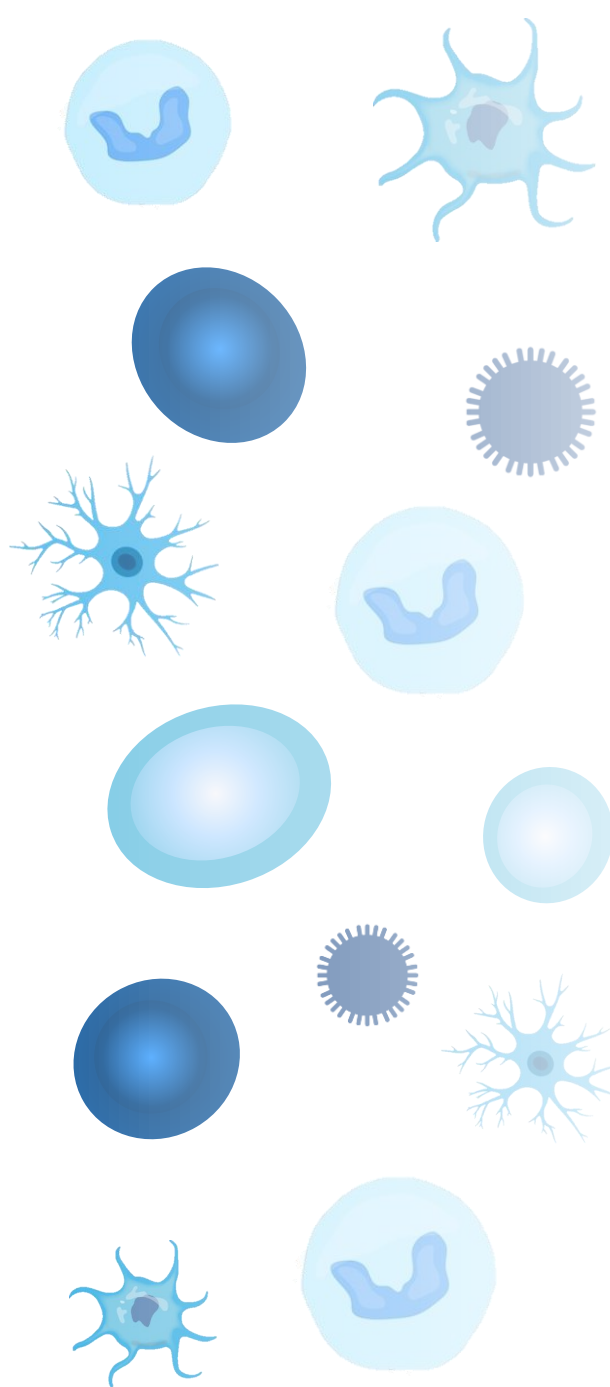
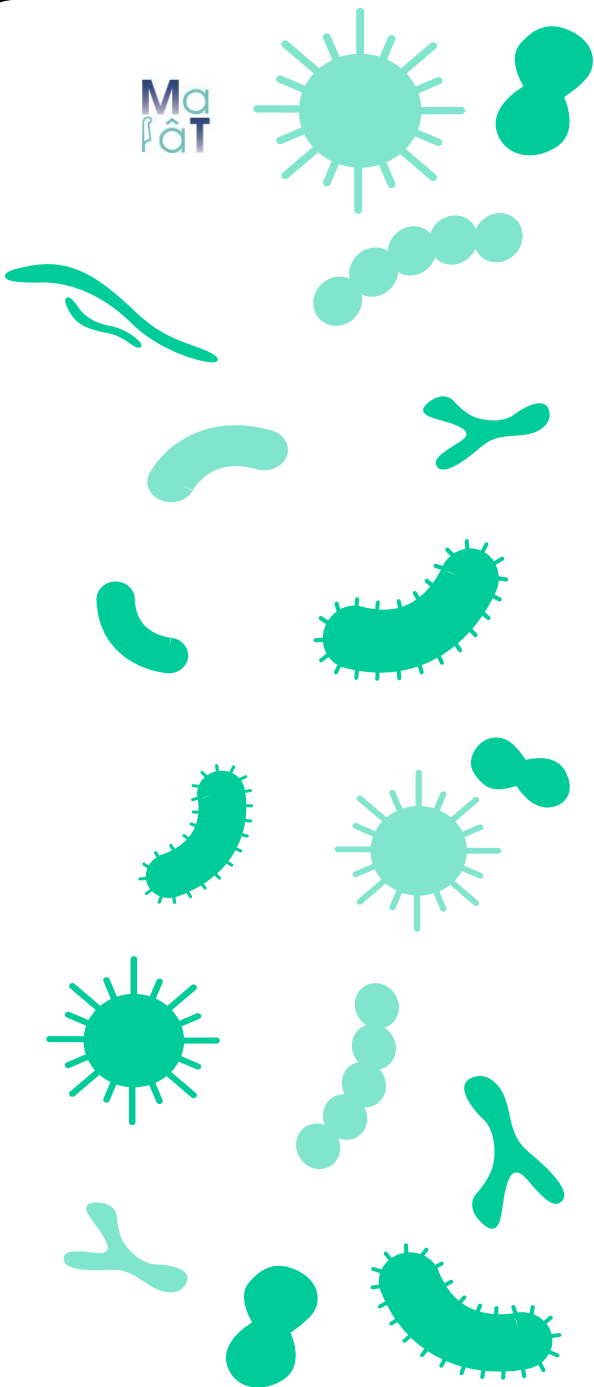


<sup>1</sup> Arthur, K., Calvo, A., Price, T. et al. Projected increase in amyotrophic lateral sclerosis - from 2015 to 2040. Nat Commun 7, 12408 (2016). <https://doi.org/10.1038/ncomms12408> <sup>2</sup> <https://tousensellescontrelasla.fr/la-sla-c'est-quoi/>

# 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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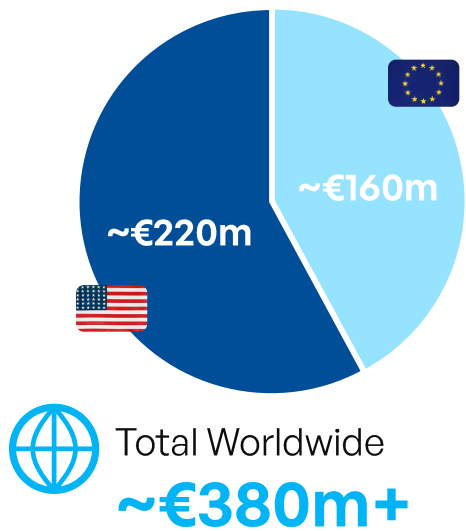
# Hemato- oncology Franchise Driving Value

# MaaT013 Addressable Market and Revenues

## Addressable market in 3L

 ~3,000 patients

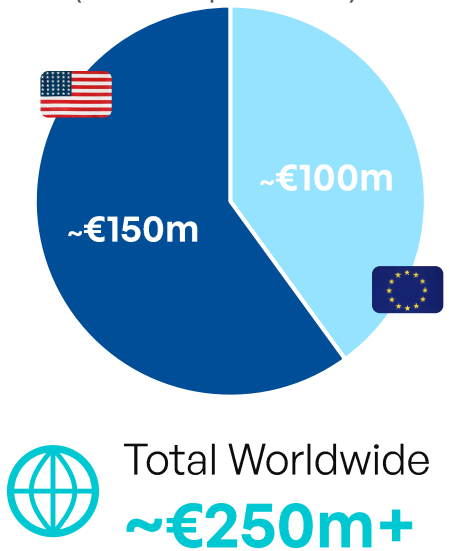
3L GI-SR-RR/I-aGvHD



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

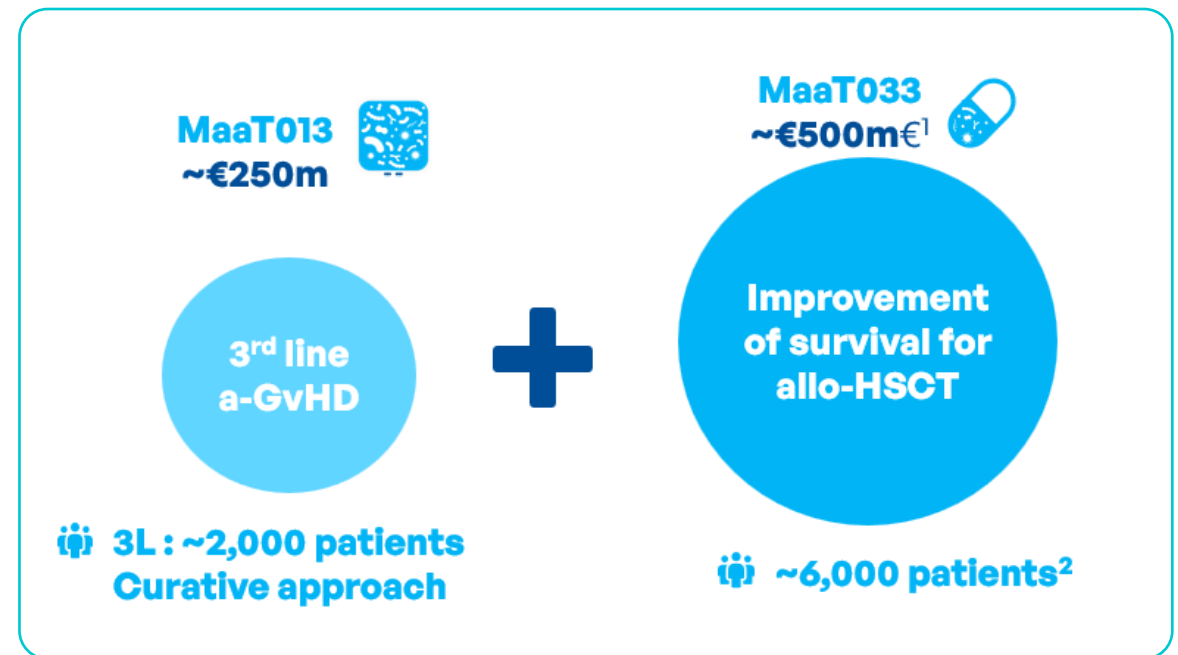
# Realizing Value through Partnership: Aligning Innovation with Unmet Medical Needs in Hematology

## 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

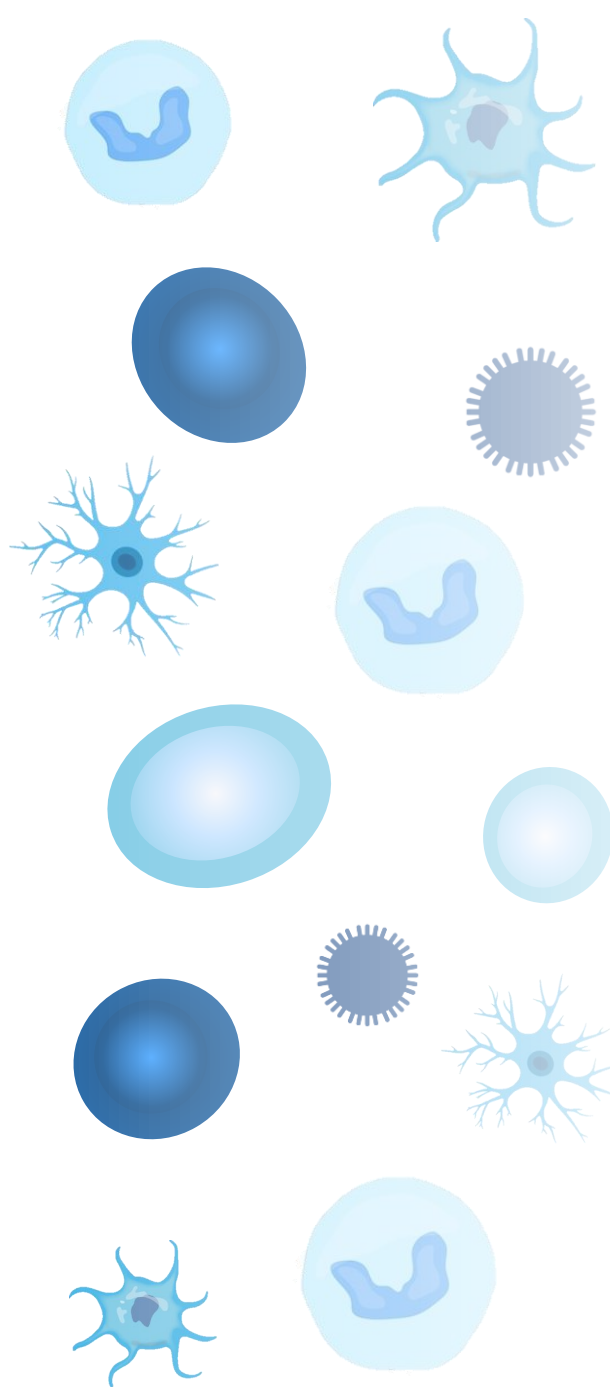
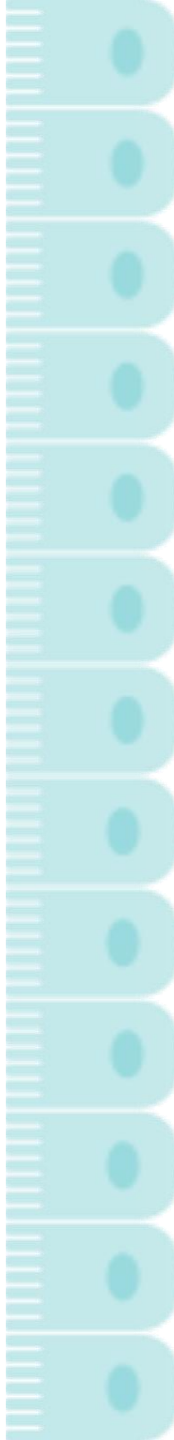
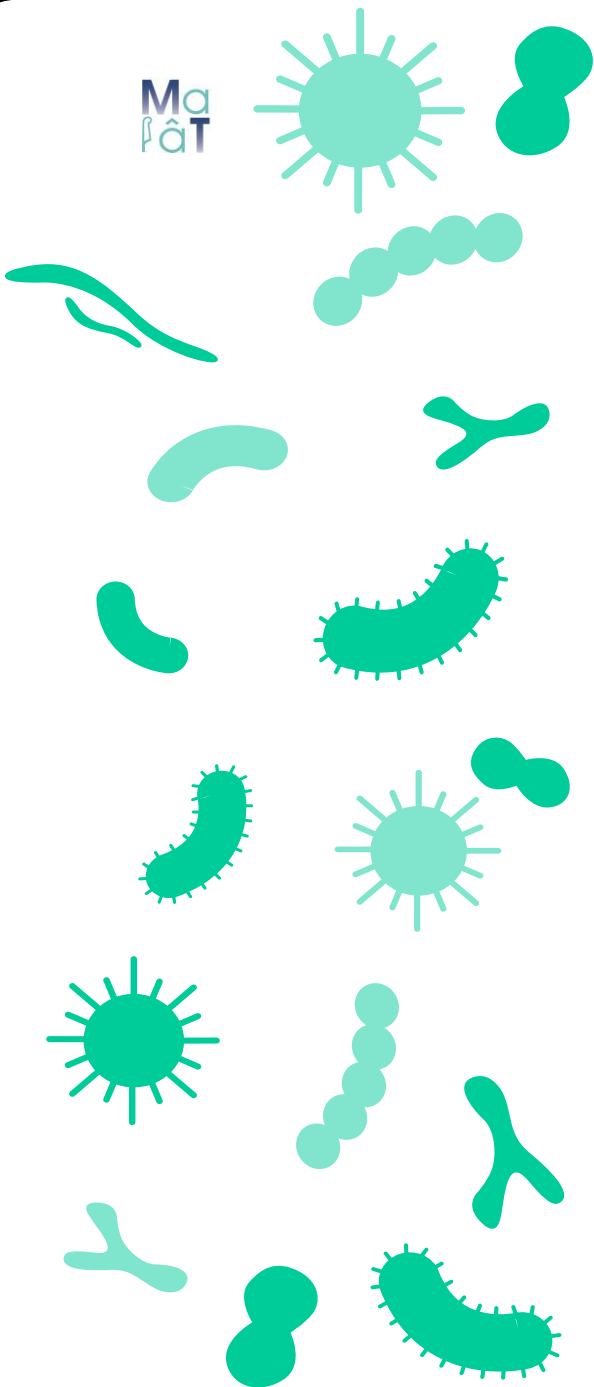
Significant potential to leverage partner's expertise in hematology, rare diseases, or hospital commercial operations.

## 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<br>bags/ year              |
| MaaT033 | 1,300,000<br>capsules / year     |
| MaaT03X | Up to 300,000<br>capsules / year |

01

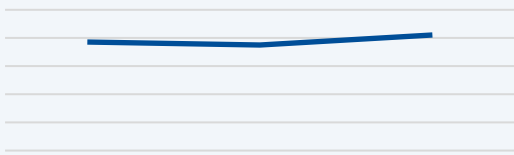
**Leading microbiome therapies fully integrated manufacturing and development platform:**  
streamlined product development, scaleup and GMP process.

02

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

03

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

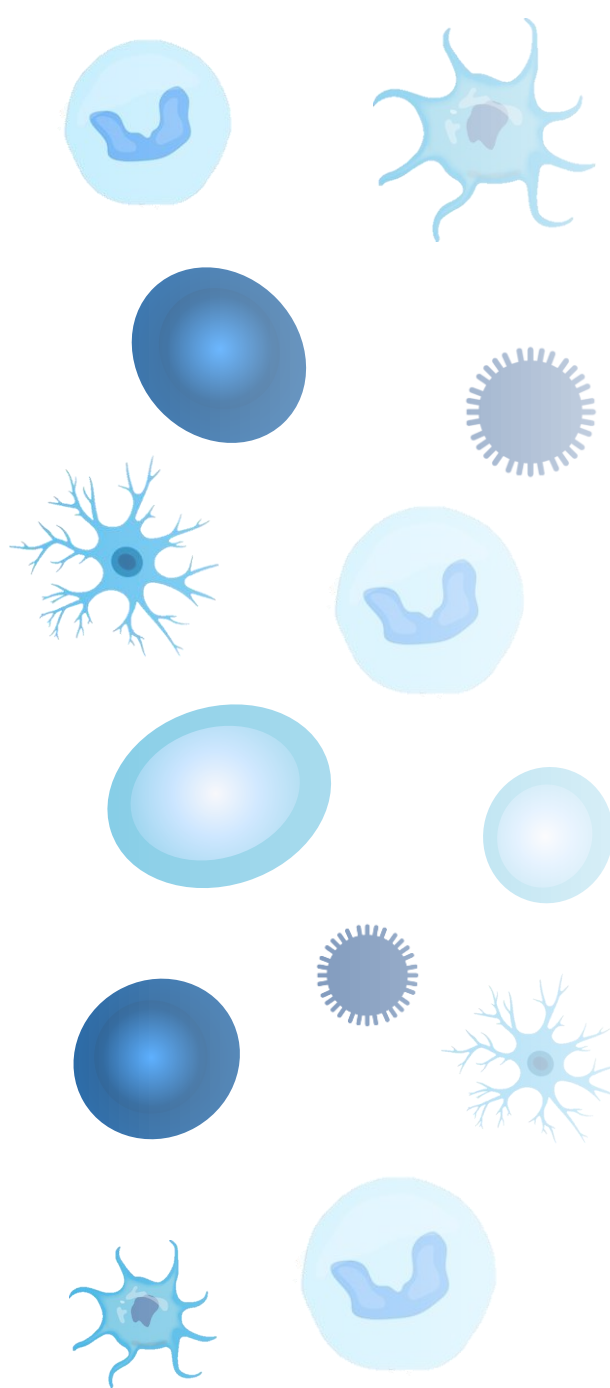
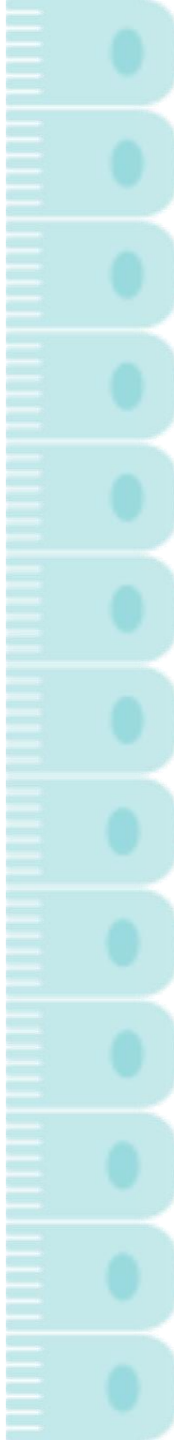
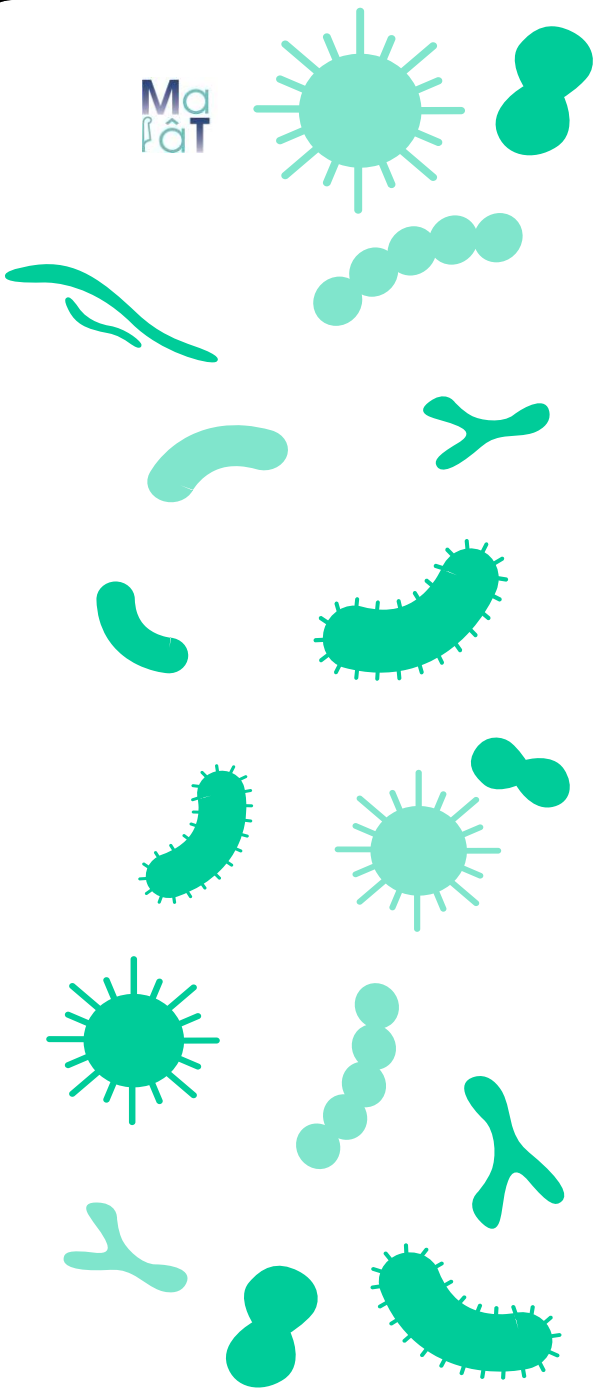


Campaign #1 Campaign #2 Campaign #3  
Manufacturing yield based on FDA/EMA authorized processes

04

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





# Newsflow & Funding Opportunities

# Several Major Near-Term Value Inflection Milestones

2025

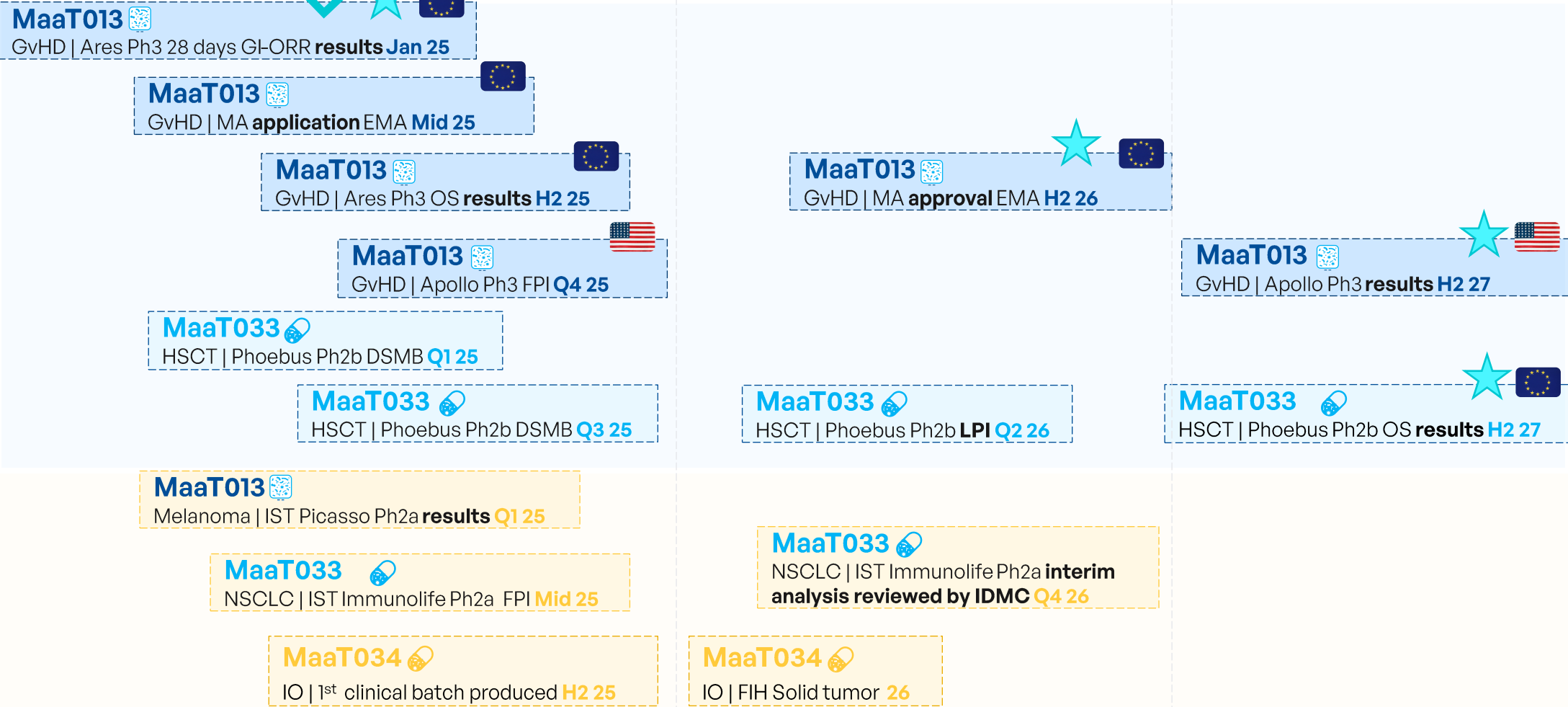
2026

2027



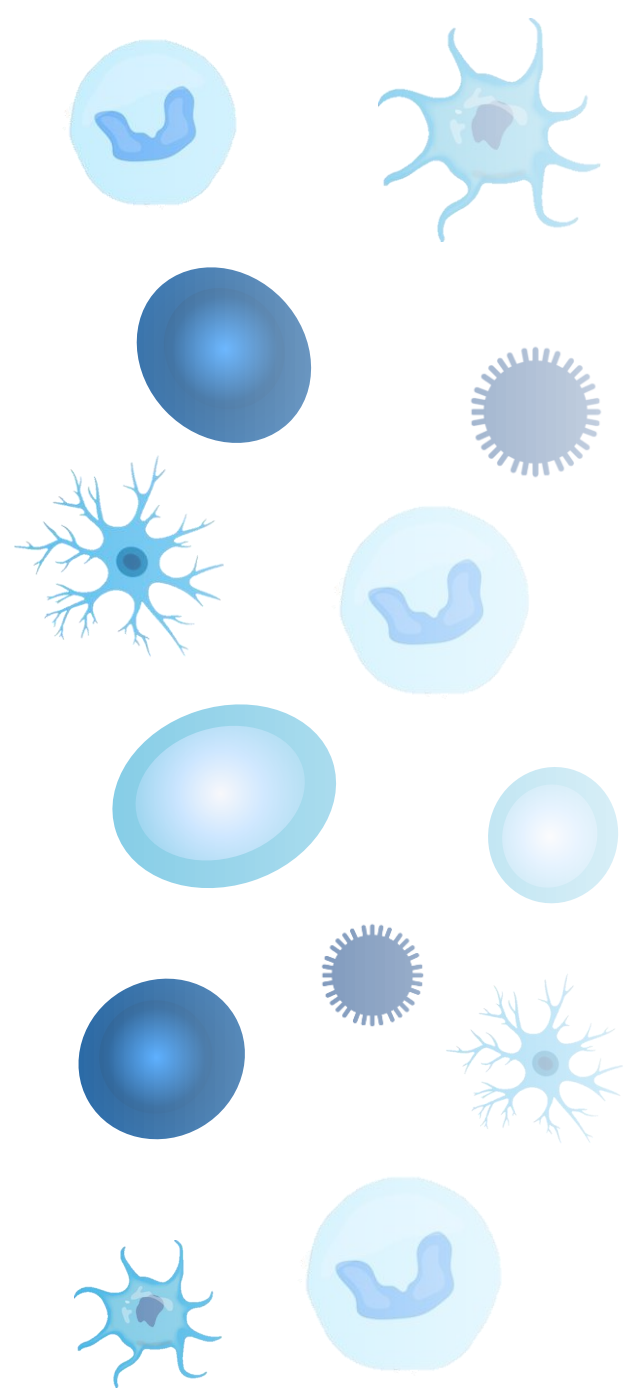
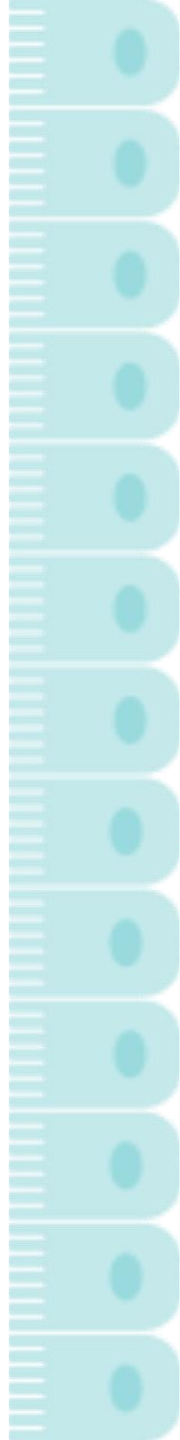
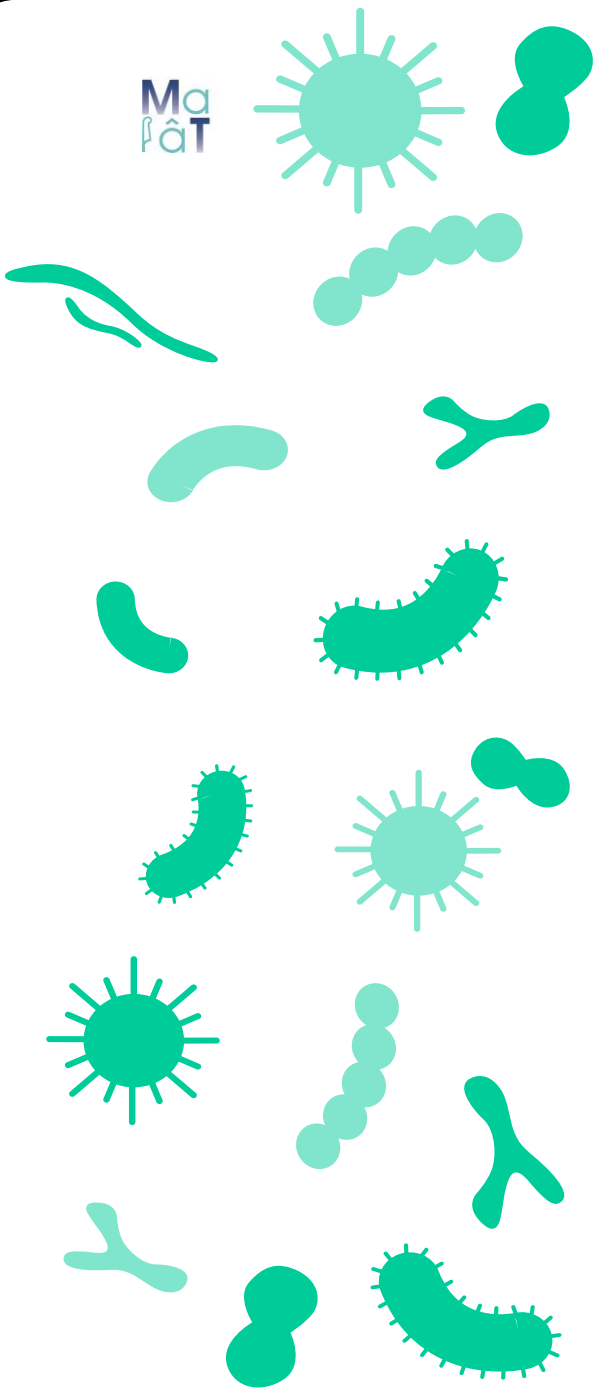
Hemato  
-  
Oncology

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

