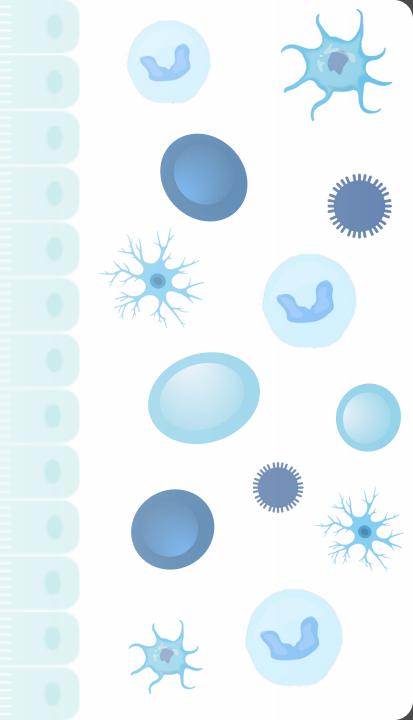


MaaT Pharma

# Boosting Survival Through Innovative Immune Modulation





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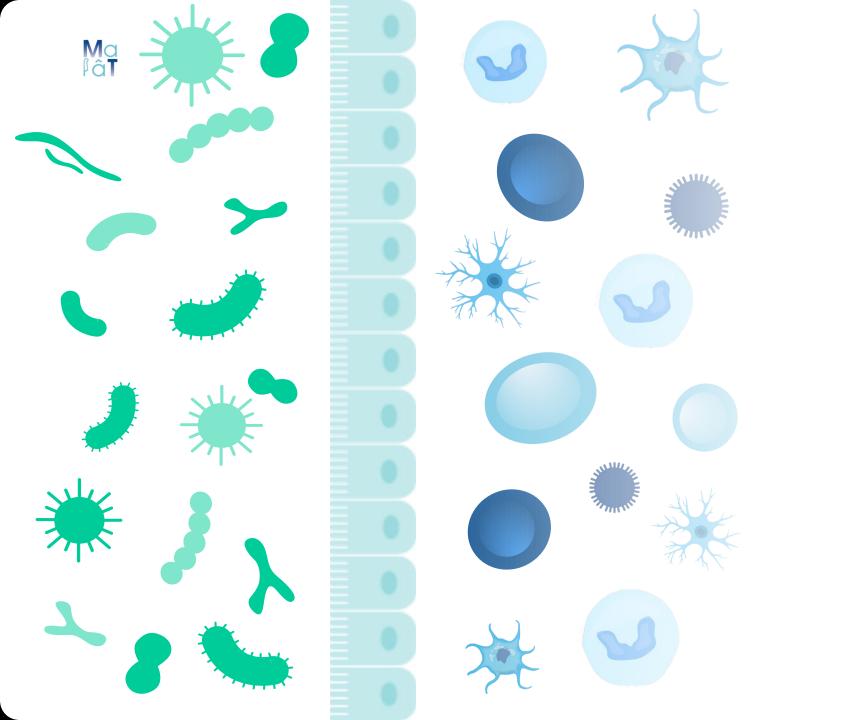
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#### **Management Team**





# **Company Overview**

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



# <u>Now available:</u> Phase 3 Data in aGvHD from the ARES study

$\diamond$	Primary endpoint: unprecedented,
	GI-ORR <sup>*</sup> of <b>62%</b> in patients having
	previously received steroids and
	ruxolitinib

> High response rate leading <b>to prolonged</b>		
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<sup>™</sup>

# 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

LISTED

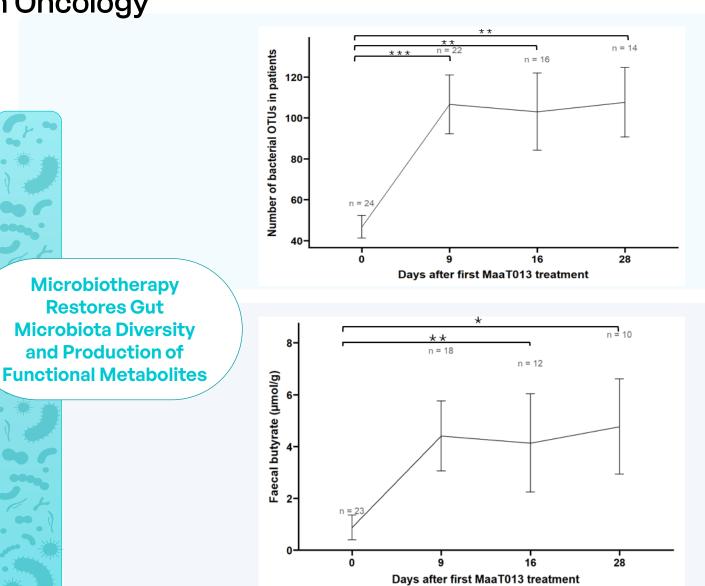
#### Correcting Dysbiosis: a New Pillar in Oncology

#### **Dysbiosis and disease**

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

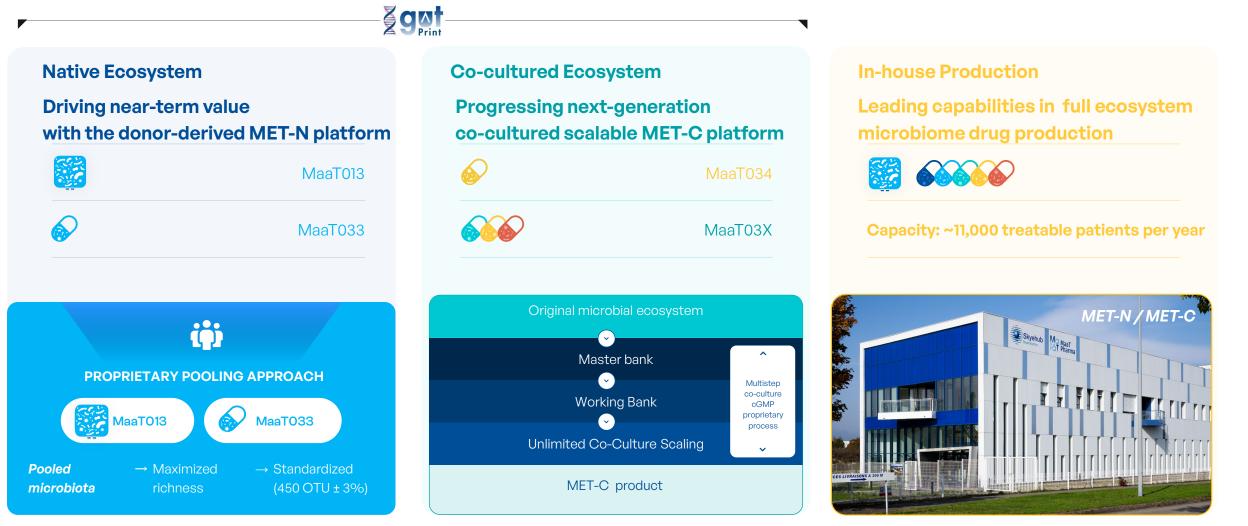
#### Microbiome alterations in Oncology

- **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



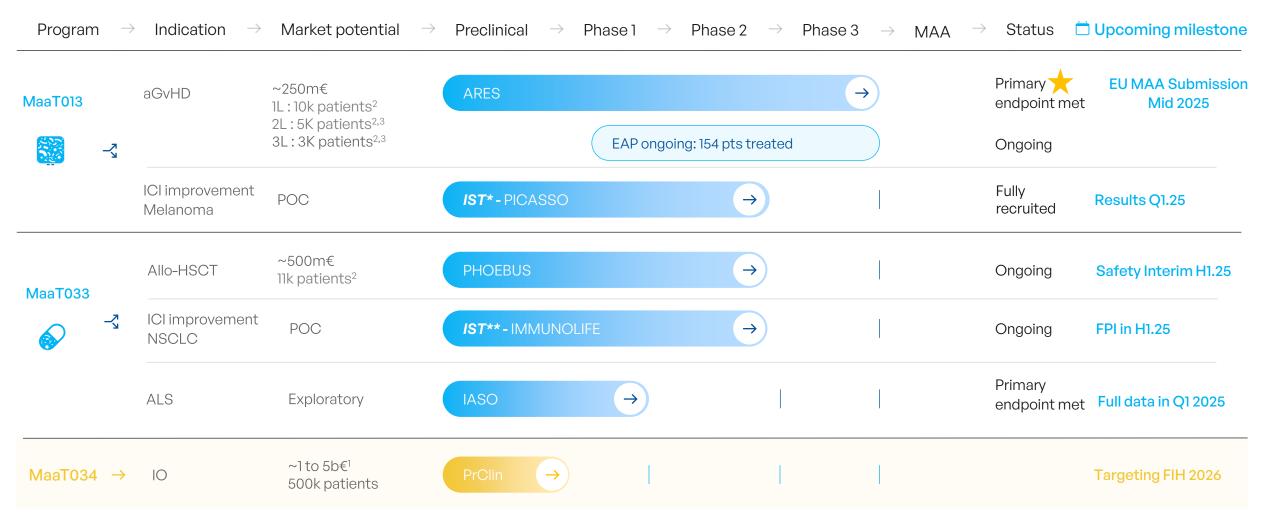
Malard, F. et al. Pooled allogeneic faecal microbiota MaaT013 for steroid-resistant gastrointestinal acute graft-versus-host disease: a single-arm, multicentre phase 2 trial. eClinicalMedicine 62, 102111 (2023).

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



A Premier Portfolio of Full Native and Co-cultured Microbiome Ecosystem Therapies<sup>™</sup> 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



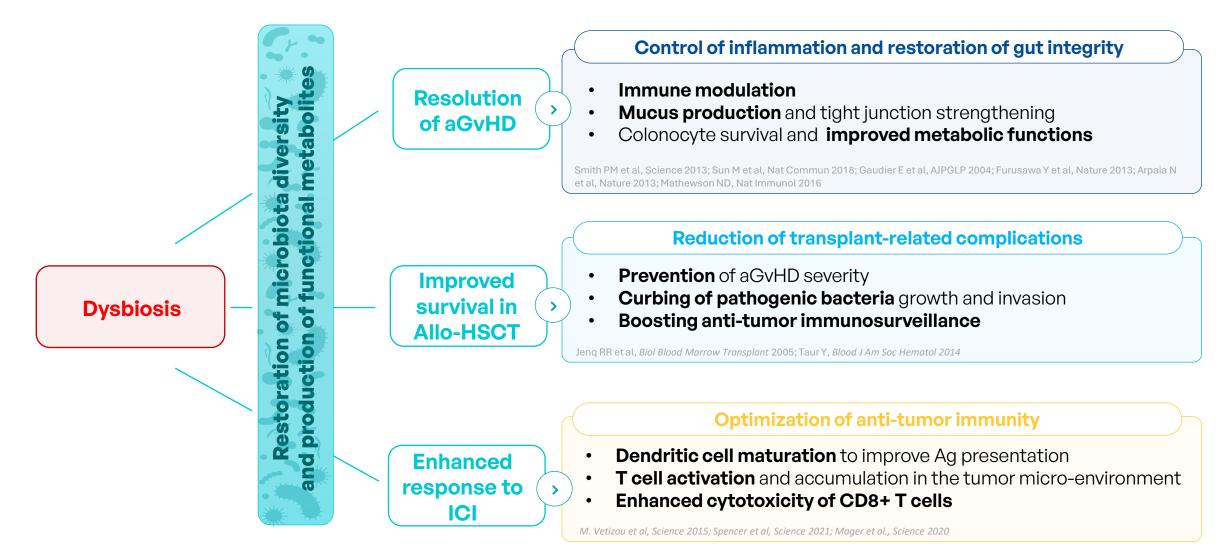
aGvHD: acute Graft versus Host Disease; IO: Immuno-Oncology; PoC: Proof of Concept; Allo-HSCT: Hematopoietic Stem Cell Transplantation; ALS: Amyotrophic Lateral Sclerosis; IST: Investigator Sponsored Trial; NSCLC: Non-small cell lung cancer

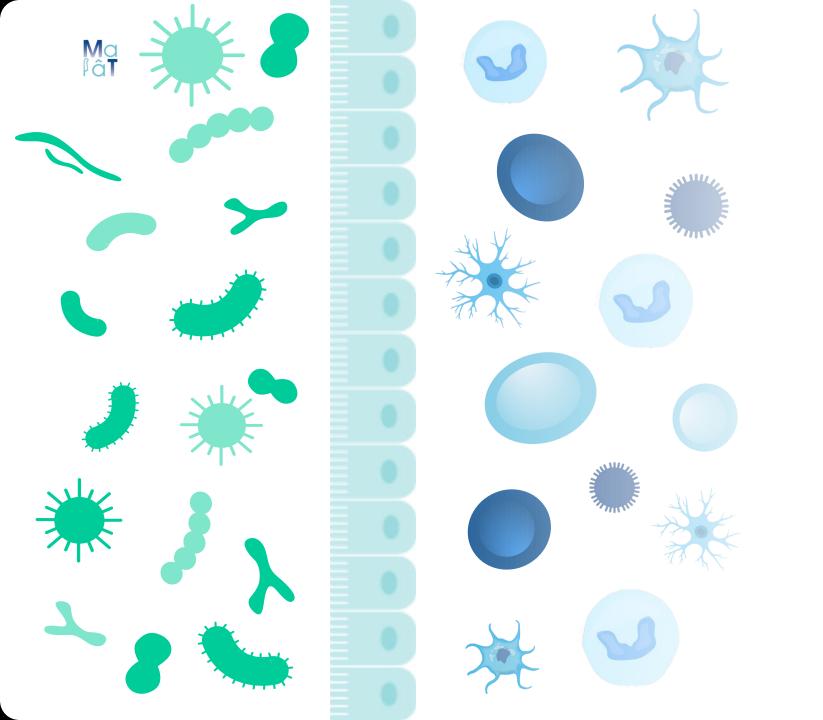
ICI PICASSO: ipilimumab (Yervoy®) and nivolumab (Opdivo®); ICI IMMUNOLIFE: cemiplimab

\* 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

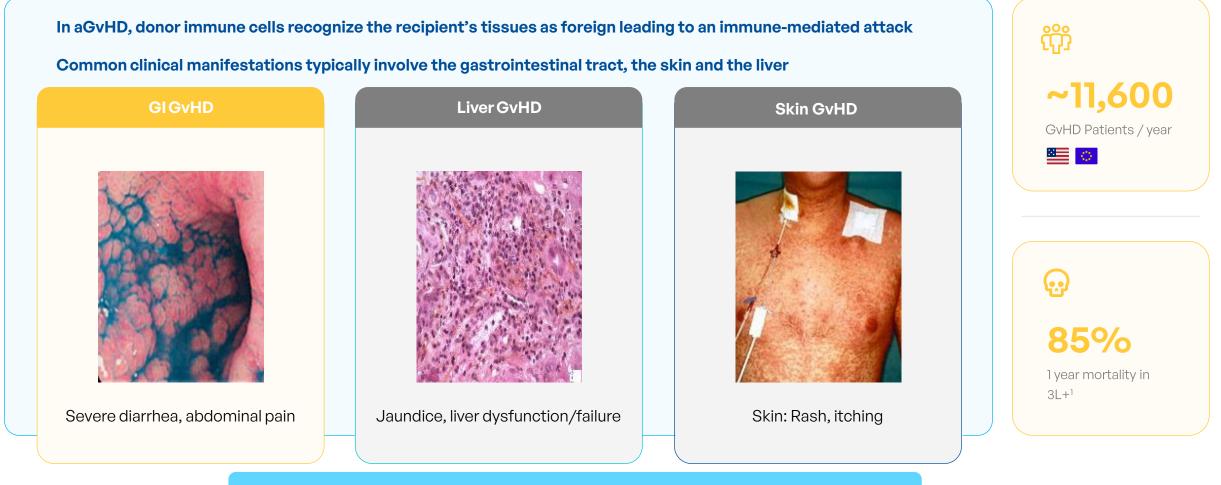




## MaaT013 in aGvHD

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

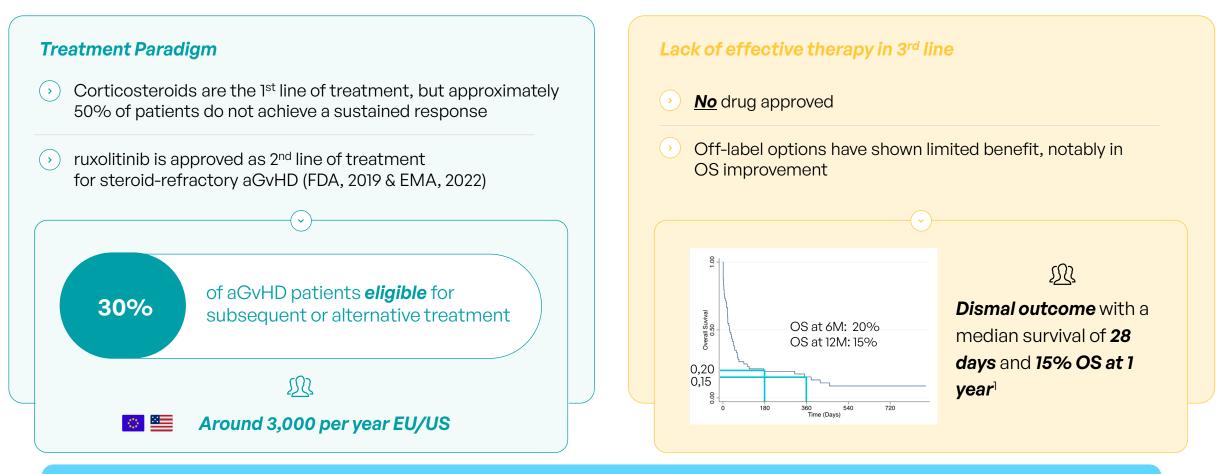
- → A significant complication following allogeneic hematopoietic stem cell transplantation (Allo-HSCT)
- → May occur in 50% of patients undergoing Allo-HSCT, presence detected typically within the first 100 days post-transplant



 $\rightarrow$  Mortality is primarily linked to the involvement of the gastrointestinal tract

→ Salvage → Ouick action

MaaT013 • aGvHD



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

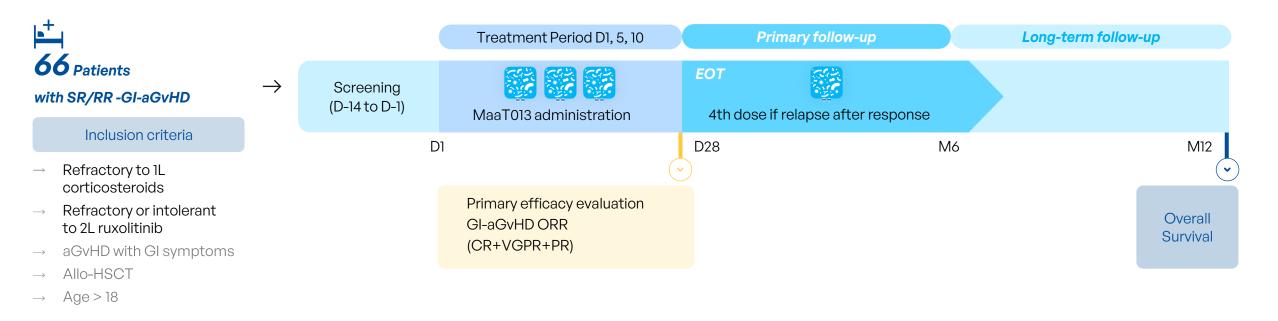
ightarrow In the Early Access Program (EAP), MaaT013 showed efficacy in aGvHD patients who failed 1 to 6 lines of systemic treatment<sup>3</sup>

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

→ Quick action

MaaT013 • aGvHD

Milestones: Topline results announced January 8th 2025 | OS expected by end of 2025 | Regulatory submission expected mid-2025





ARES

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#### **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 (%)	ruxolitinib refractory: 66 (100%)
	ruxolitinib intolerant: 0
aGvHD grading (MAGIC*)	Grade I: 0
	Grade II: 6 (9%)
	Grade III: 38 (58%)
	Grade IV: 22 (33%)

🕮 Patients with severe aGvHD

#### 91% are Grade III-IV

\*MAGIC : Mount Sinai Acute GVHD International Consortium

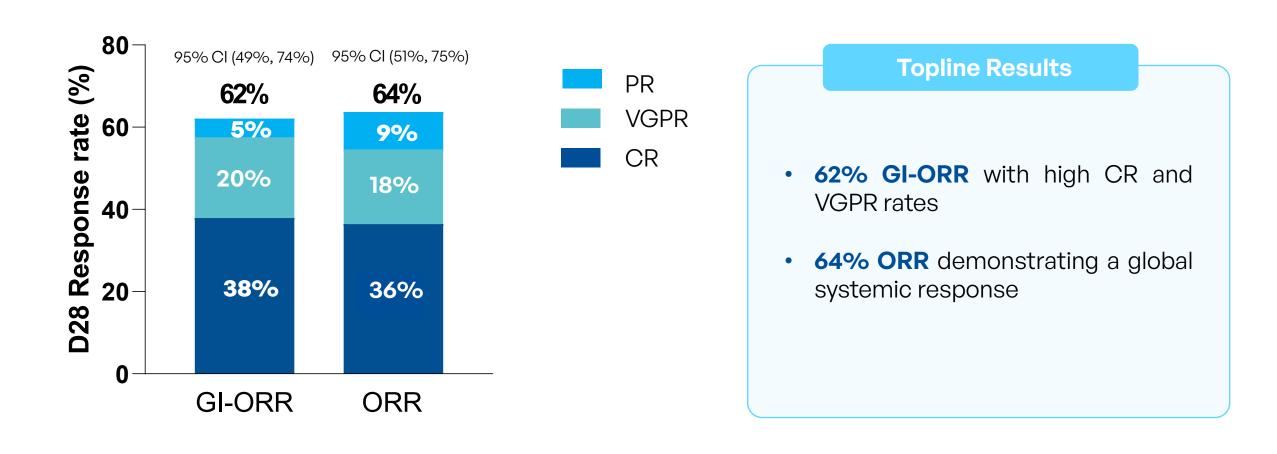
#### 100% are ruxolitinib refactory

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

MaaT013 • aGvHD
 ODD EMA/FDA

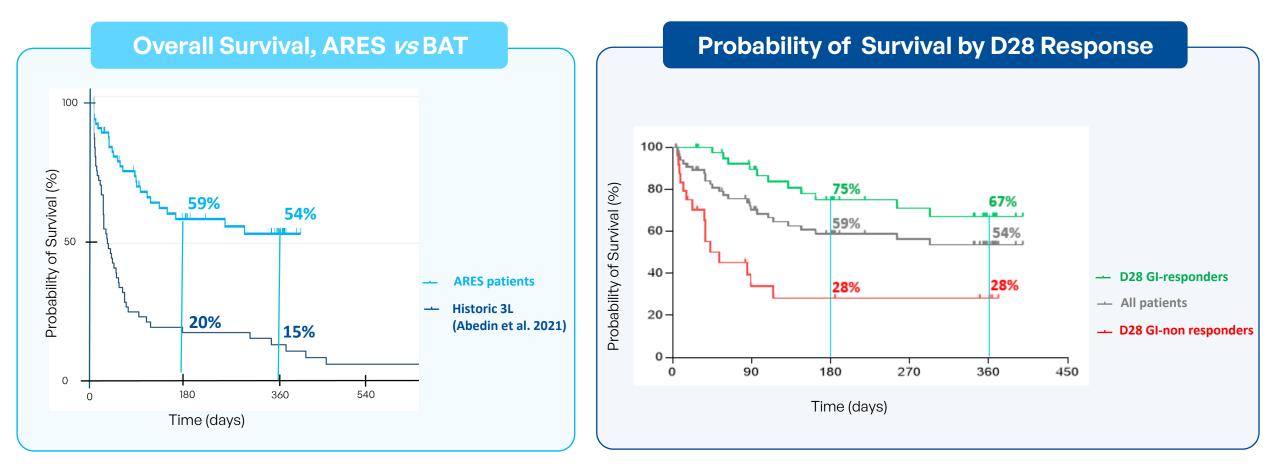
Quick action



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

MaaT013 • aGvHD

**Ouick** action

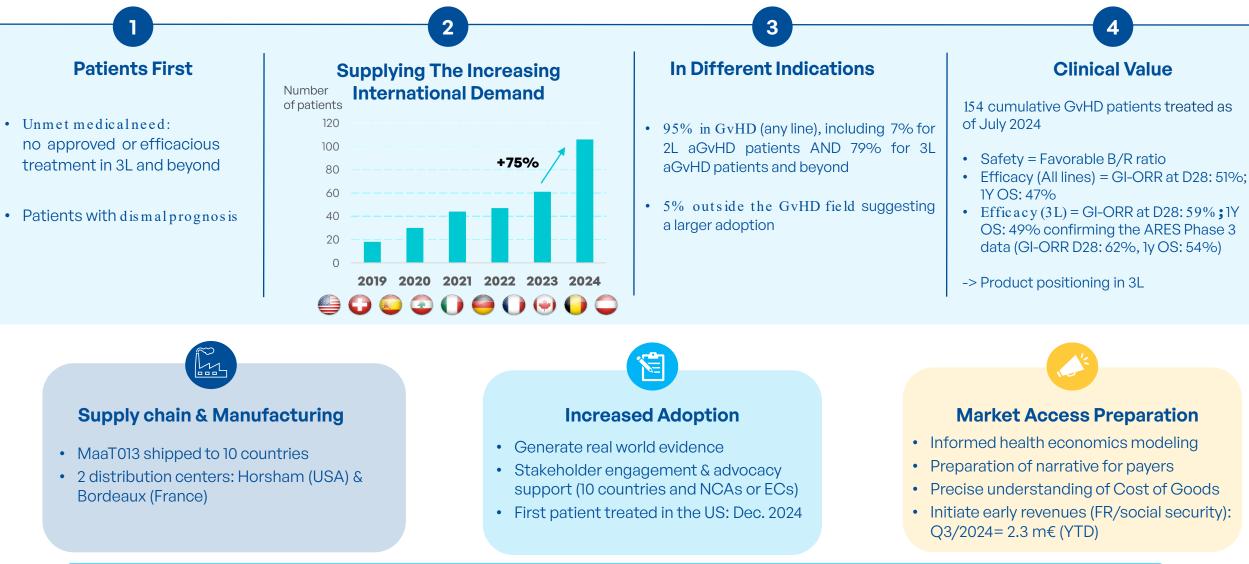


MaaT013 demonstrates response-driven prolonged survival, far exceeding expected outcomes in thirdline aGvHD, with **54% probability of survival at 1 year compared to 15% survival in historical control** 

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

MaaT013 • aGvHD

Quick action



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

## Clear Regulatory Path for MaaT013 in Third Line Refractory aGvHD

- 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

- 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

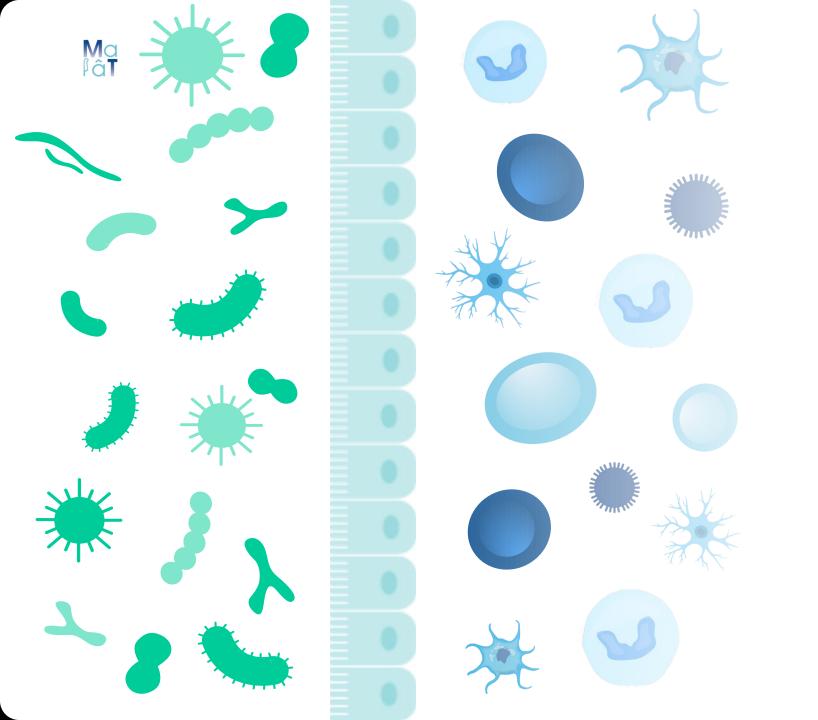






**Ouick** action

MaaT013 • aGvHD



A Multi-Asset Platform Focused on Oncology

## Phoebus: MaaTO33 Phase 2b RCT Potential Adjunctive Treatment for Patients Receiving Allo-HSCT

Design presented at EBMT and ASH



#### Largest Microbiome RCT trial in oncology

→ Ambulatory

Adjunctive

- → Multicenter Randomized Control Trial
- $\rightarrow$  56 sites / 6 countries

- → Primary endpoint: **1y-OS**
- $\rightarrow$  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 patientsper 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)

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

✓ 15/20

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

PICASSO studying MaaT013: 1<sup>st</sup> multicenter RCT **70 pts rand 1:1**  21

### 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)

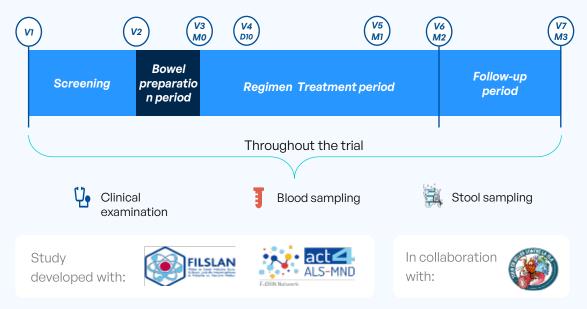
- ightarrow Could affect up to 60,000 patients in US & EU by 2040<sup>1</sup>
- $\rightarrow$   $\,$  Paralysis and death 3 to 5 years after diagnostic  $^2$
- $\rightarrow$  Currently no curative treatment and few symptomatic treatments

#### Rationale for Exploratory Utilization of MaaT033 in ALS

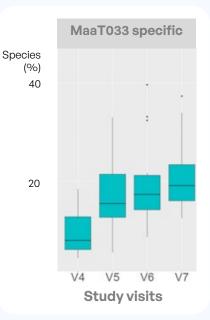
- Microbiota-Gut-Brain axis is a multifactorial MoA which has the potential to become the new standard to treat neurodegenerative diseases, including ALS
- → Strong support from medical community & patients
- $\rightarrow$  A capital efficient way of testing neurodegenerative field in the most severe 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)

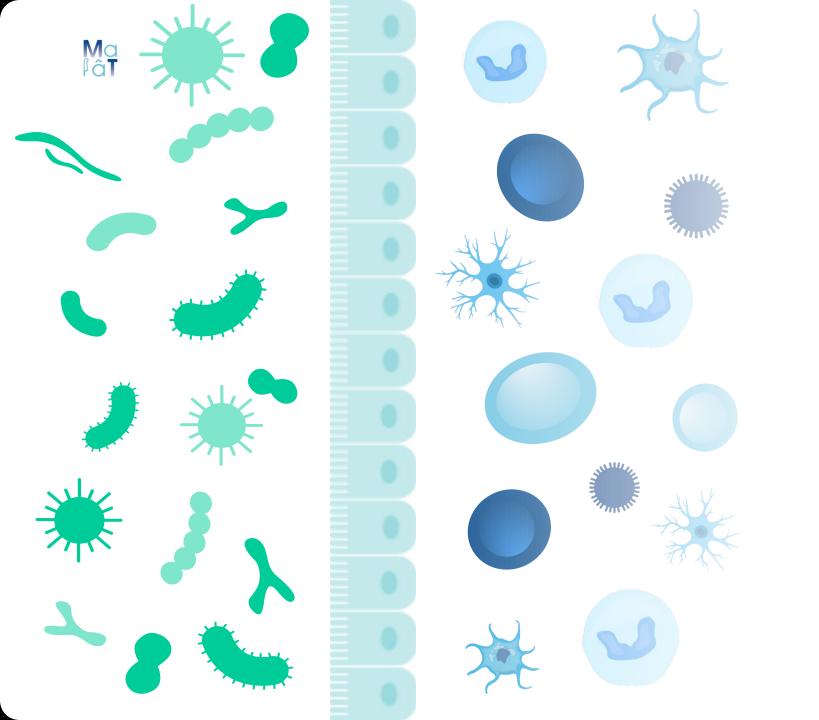


<sup>1</sup> Arthur, K., Calvo, A., Price, T. et al. Projected increase in amyotrophic lateral sclerosis – from 2015 to 2040. Nat Commun 7, 12408 (2016). <u>https://doi.org/10.1038/ncomms12408</u> I<sup>2</sup> https://tousensellescontrelasla.fr/la-sla-cest-quoi/

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

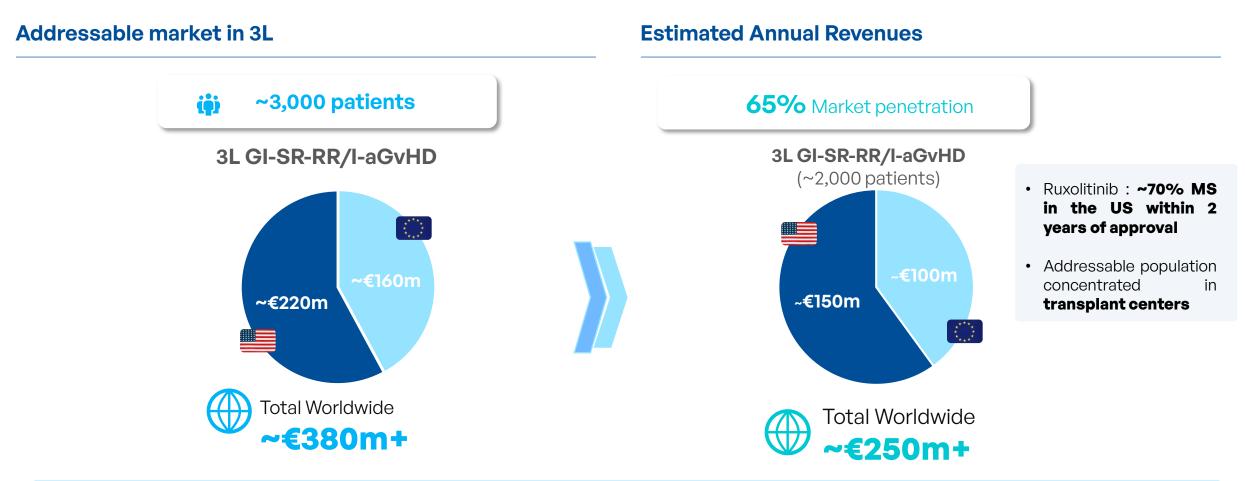
MET-C • ICI and more





Hematooncology Franchise Driving Value

#### MaaT013 Addressable Market and Revenues



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

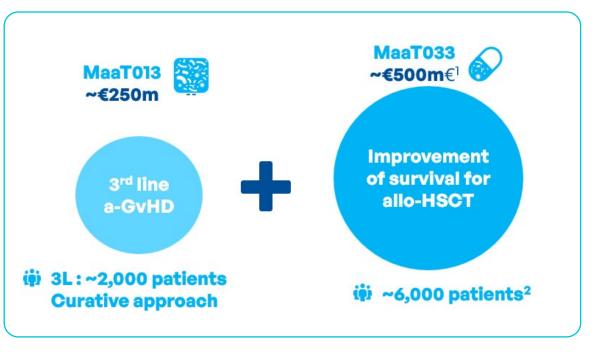
#### **Unique Franchise Opportunity**

- 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)

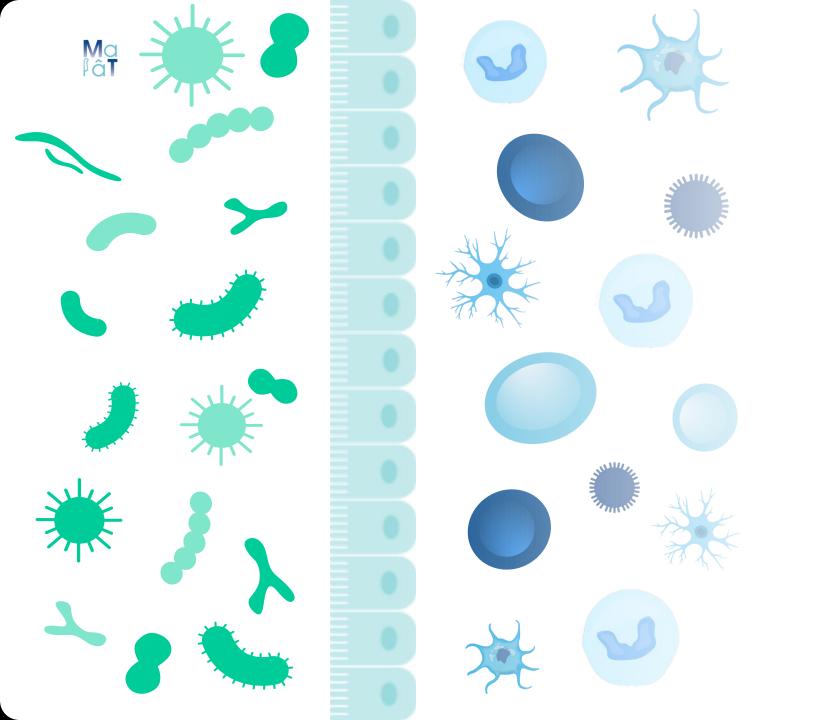
Multiple value catalysts over the next few months

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

#### A very meaningful market opportunity







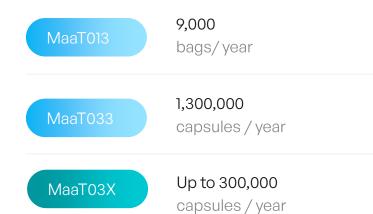
End-to-End In-house cGMP Manufacturing Capabilities

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

O AII MET

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





→ cGMP

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

streamlined product development, scaleup and GMP process.



*Option to expand manufacturing facilities* to double capabilities.



Consistent yield (<10% variation)

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

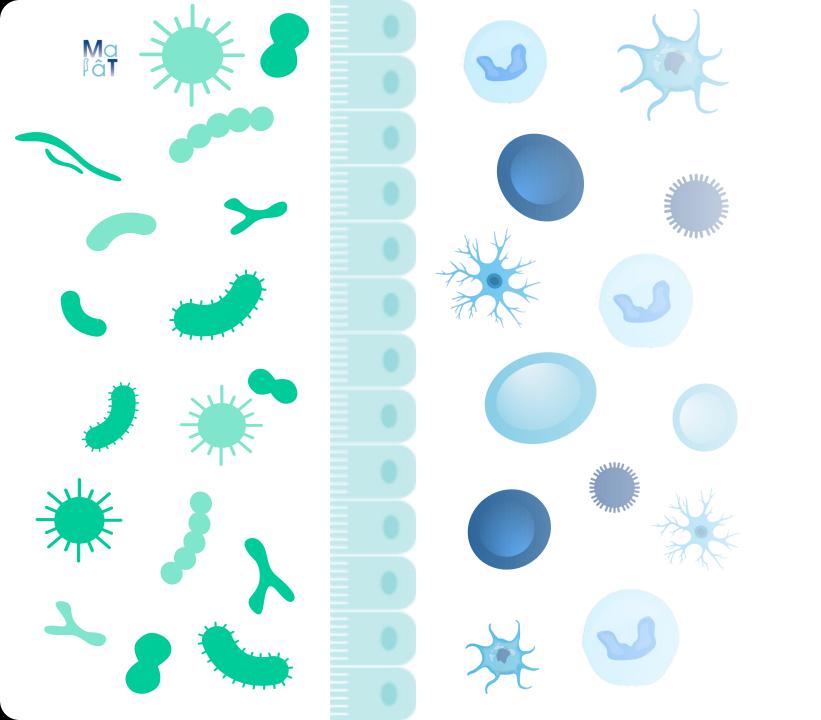


Currently used at 10% capacity **Scalable up to commercial capacity** 

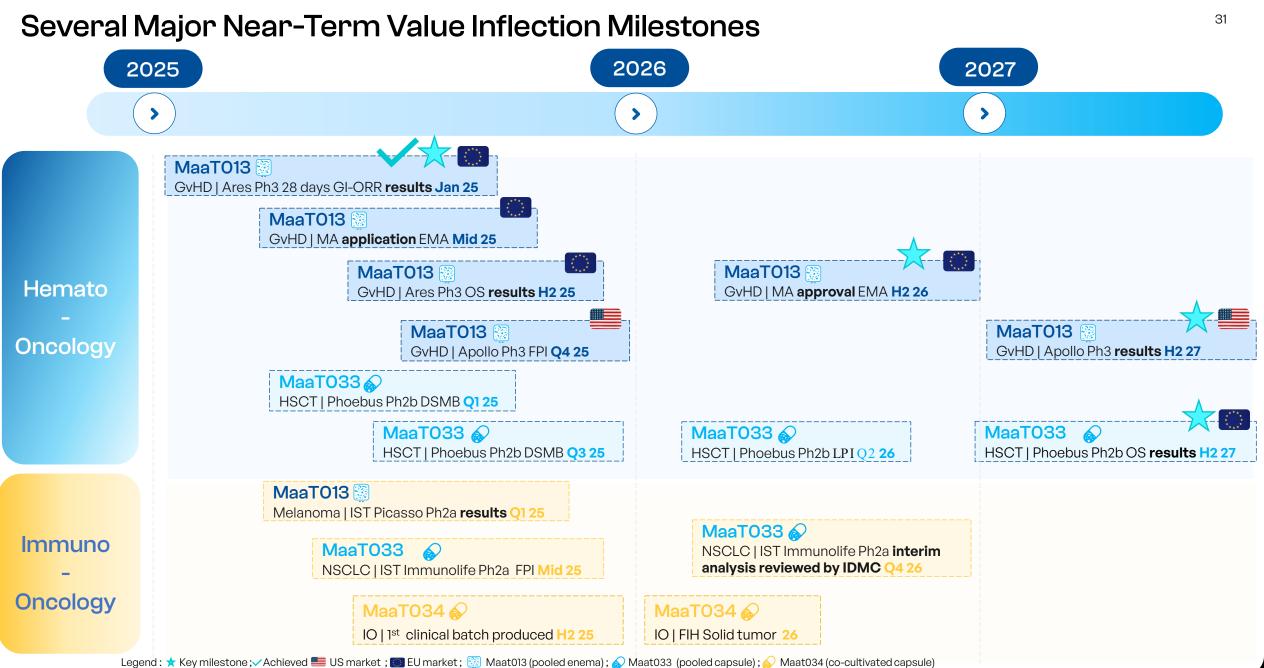


Partnership with





# Newsflow & Funding Opportunities



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### Opportunities to fund the Company's development

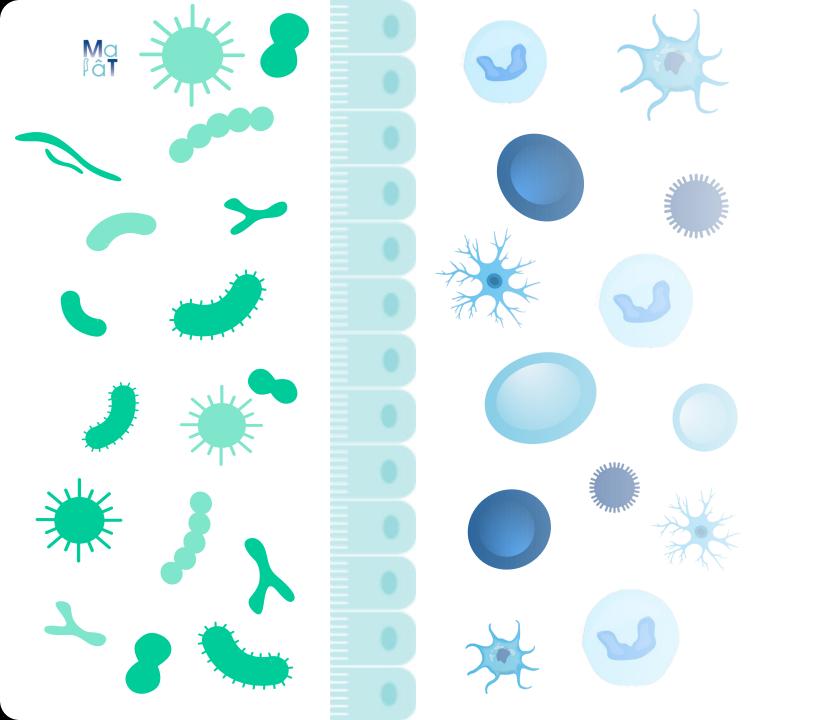
Cash position of €27m as of September 30,2024

>

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** 





# Thank you

