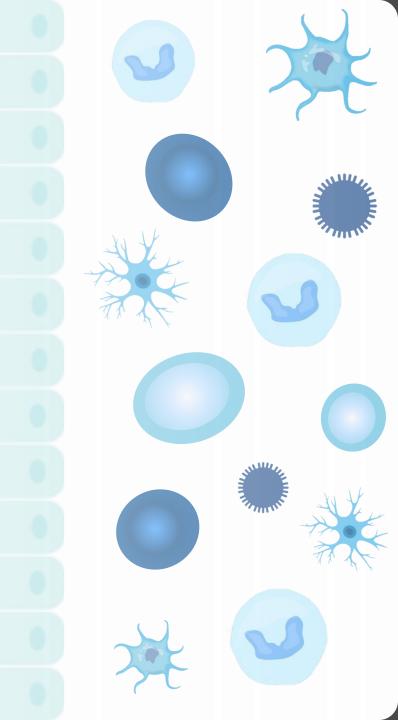


MaaT Pharma

# Boosting Survival Through Innovative Immune Modulation



EURONEX



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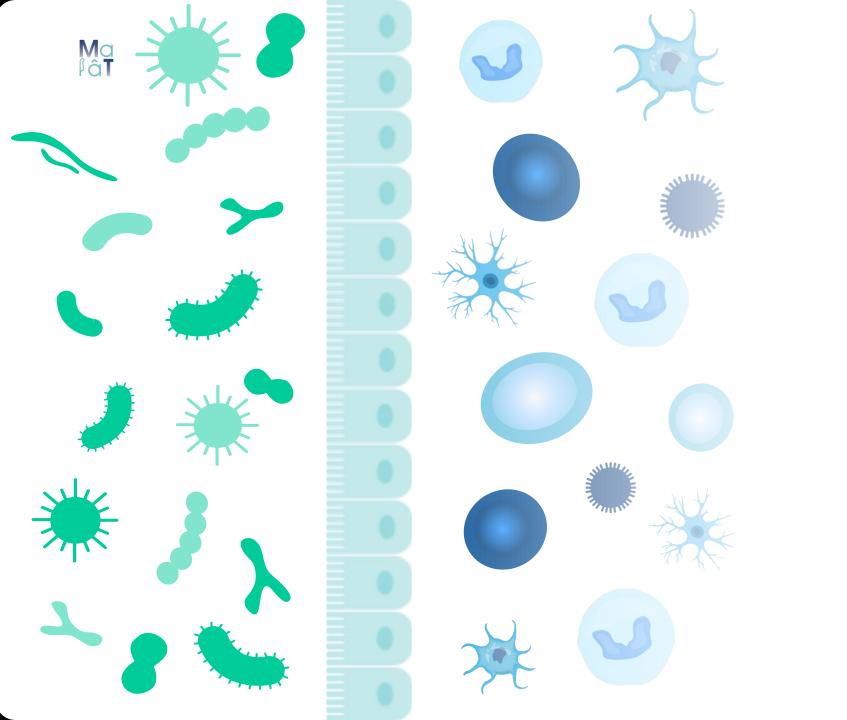
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#### **Management Team**





# **Company Overview**

LISTED

### 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

$\rightarrow$	Primary endpoint: unprecedented,	
	GI-ORR <sup>*</sup> of <b>62%</b> 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<sup>TM</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

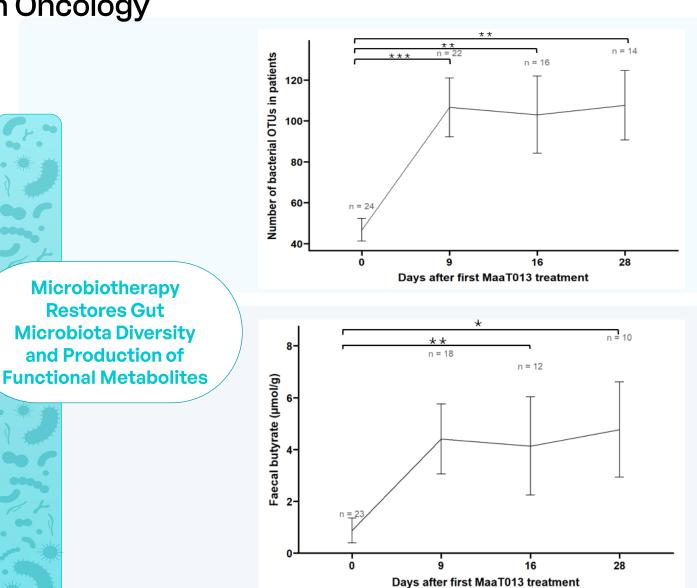
#### Correcting Dysbiosis: a New Pillar in Oncology

#### **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



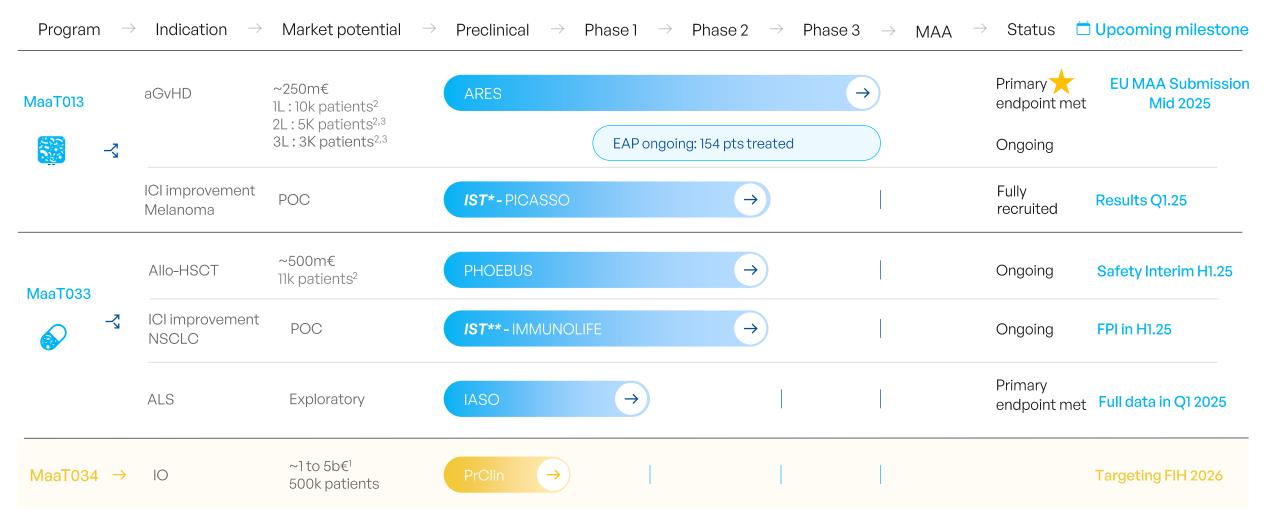
Malard, F. et al. Pooled allogeneic faecal microbiota MaaT013 for steroid-resistant gastrointestinal acute graft-versus-host disease: a single-arm, multicentre phase 2 trial. eClinicalMedicine 62, 102111 (2023).

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



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



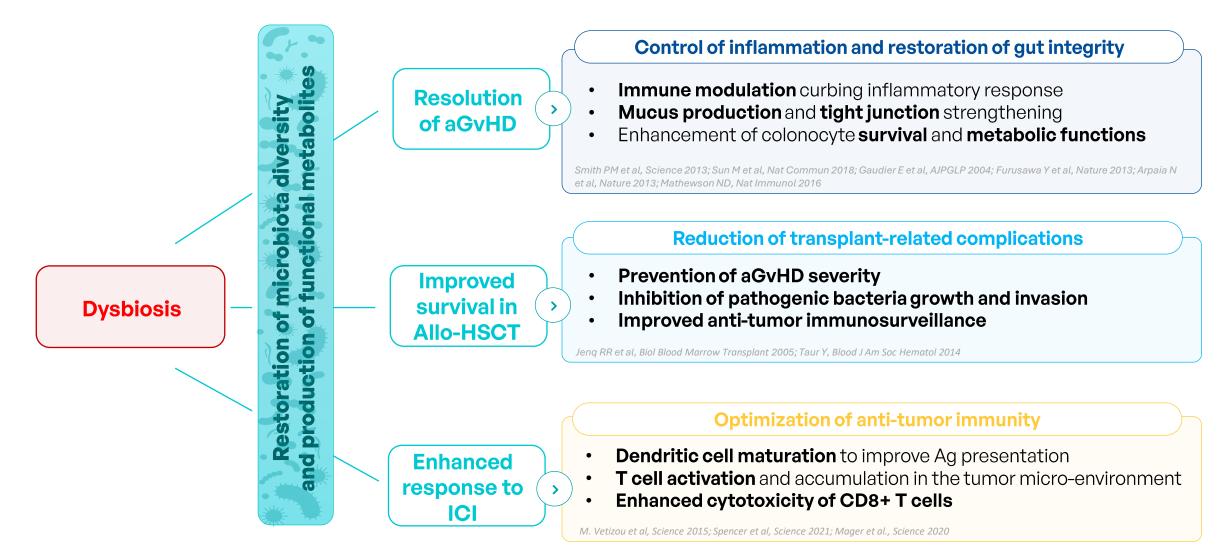
aGvHD: acute Graft versus Host Disease; IO: Immuno-Oncology; PoC: Proof of Concept; Allo-HSCT: Hematopoietic Stem Cell Transplantation; ALS: Amyotrophic Lateral Sclerosis; IST: Investigator Sponsored Trial; NSCLC: Non-small cell lung cancer

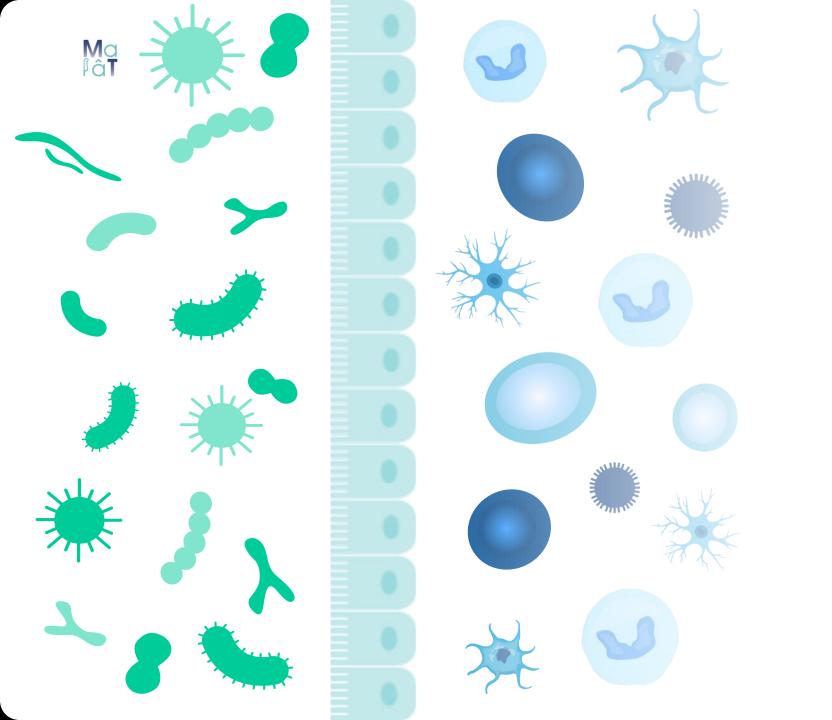
ICI PICASSO: ipilimumab (Yervoy®) and nivolumab (Opdivo®); ICI IMMUNOLIFE: cemiplimab

\* 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

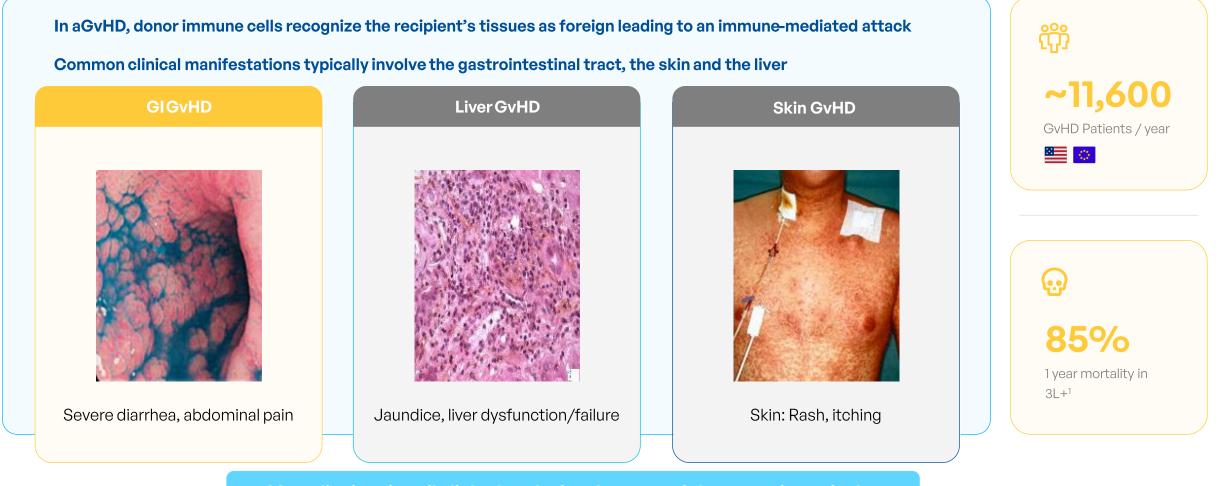
#### Understanding and Addressing Acute Graft-versus-Host Disease (aGvHD)

→ A significant complication following allogeneic hematopoietic stem cell transplantation (Allo-HSCT)

**Ouick** action

MaaT013 • aGvHD

→ May occur in 50% of patients undergoing Allo-HSCT, presence detected typically within the first 100 days post-transplant

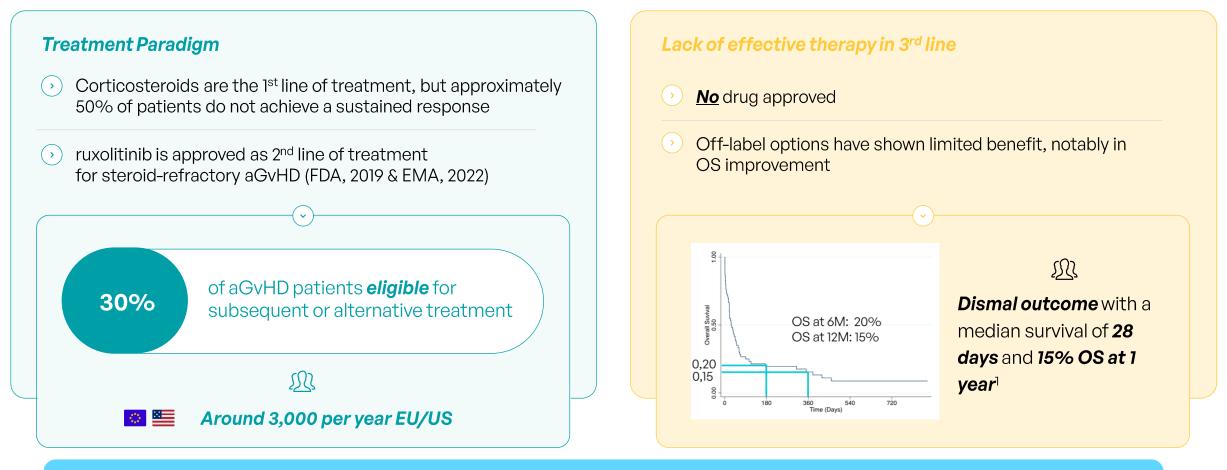


ightarrow Mortality is primarily linked to the involvement of the gastrointestinal tract

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

MaaT013 • aGvHD

→ Salvage → Ouick action



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

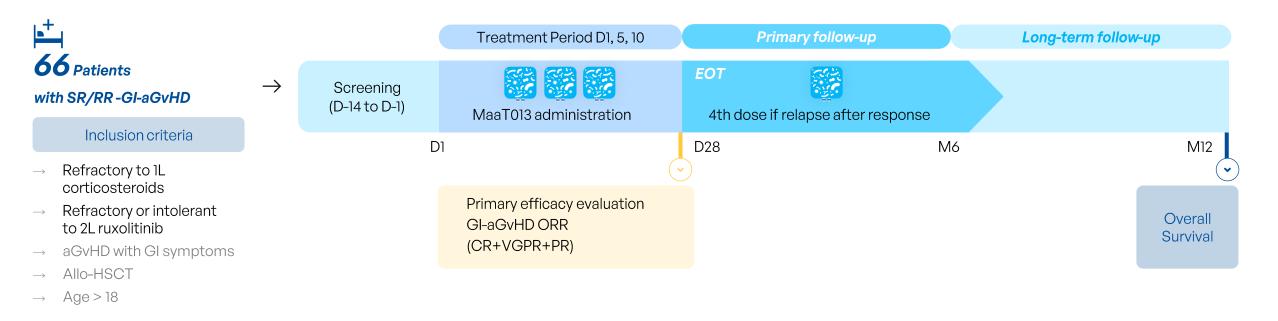
ightarrow In the Early Access Program (EAP), MaaT013 showed efficacy in aGvHD patients who failed 1 to 6 lines of systemic treatment $^3$ 

# 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

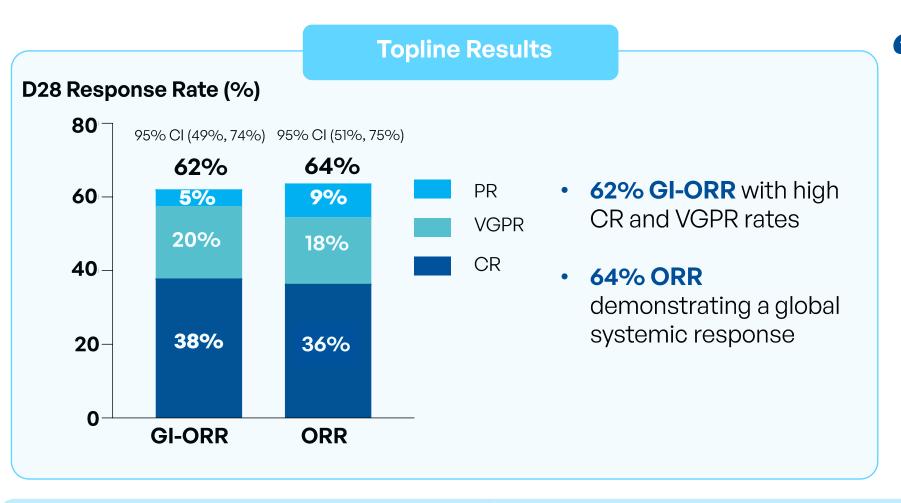
#### 91% are Grade III-IV

\*MAGIC : Mount Sinai Acute GVHD International Consortium

#### 100% are ruxolitinib refactory

January 2025

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



MaaT013 • aGvHD

Salvage
 Ouick action

These outcomes underscore the curative role of microbiotabased 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

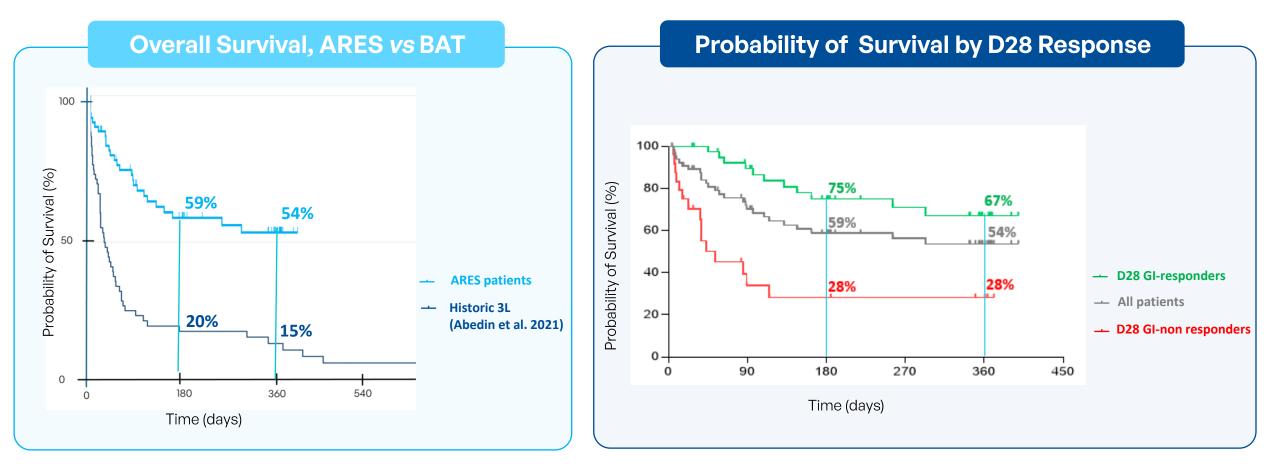


The study met its primary endpoint with a significant gastrointestinal overall response rate (p < 0.0001)

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

MaaT013 • aGvHD

Salvage
 Ouick action

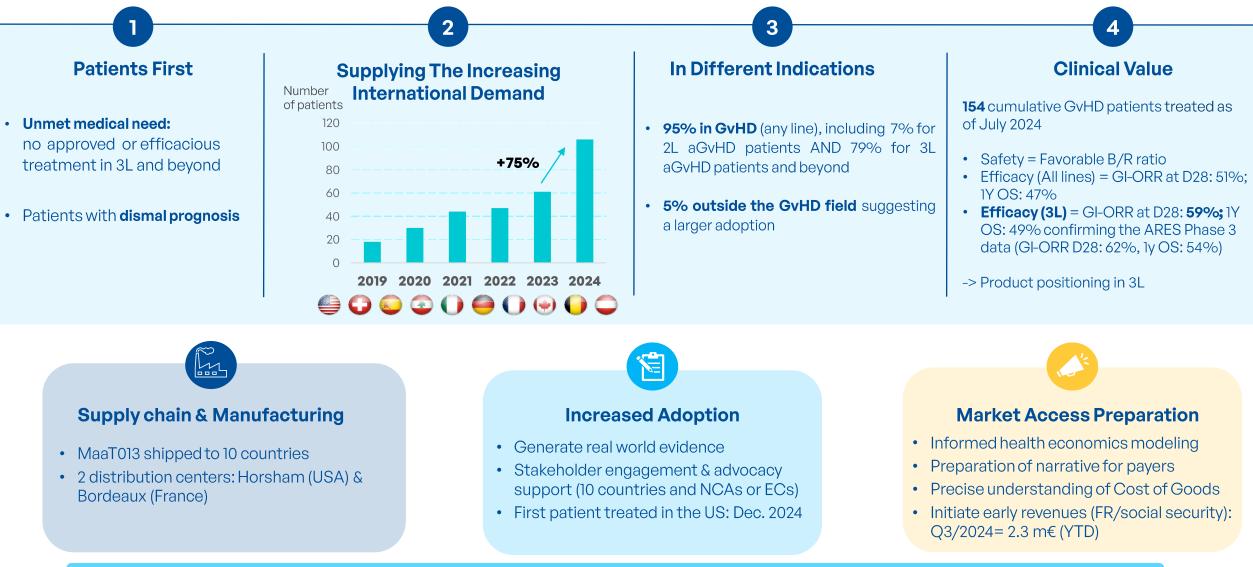


MaaT013 demonstrates response-driven prolonged survival, far exceeding expected outcomes in thirdline aGvHD, with **54% probability of survival at 1 year compared to 15% survival in historical control** 

#### 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

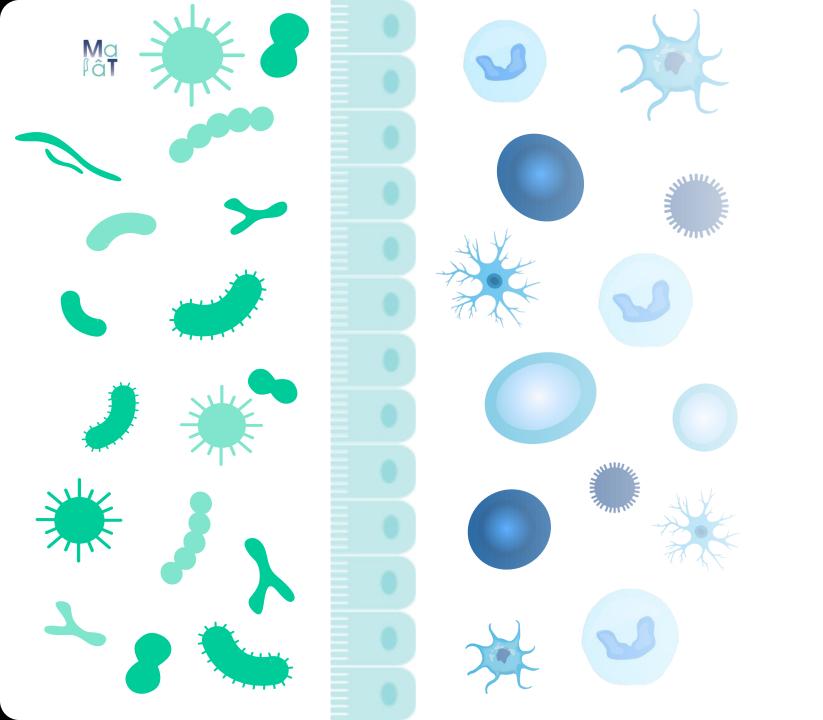
Ouick action

MaaT013 • aGvHD

- 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





A Multi-Asset Platform Focused on Oncology

EBMT

## 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

MaaT033 • Allo-HSCT

- → 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 Q12025 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)

⊘ 3/10

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

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

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

#### Phase 2a PICASSO trial, <u>fully recruited</u>

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

#### $\rightarrow$ 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



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### 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
- $\rightarrow$  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

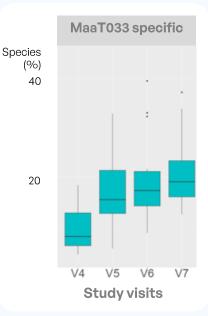
#### Study

→ 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

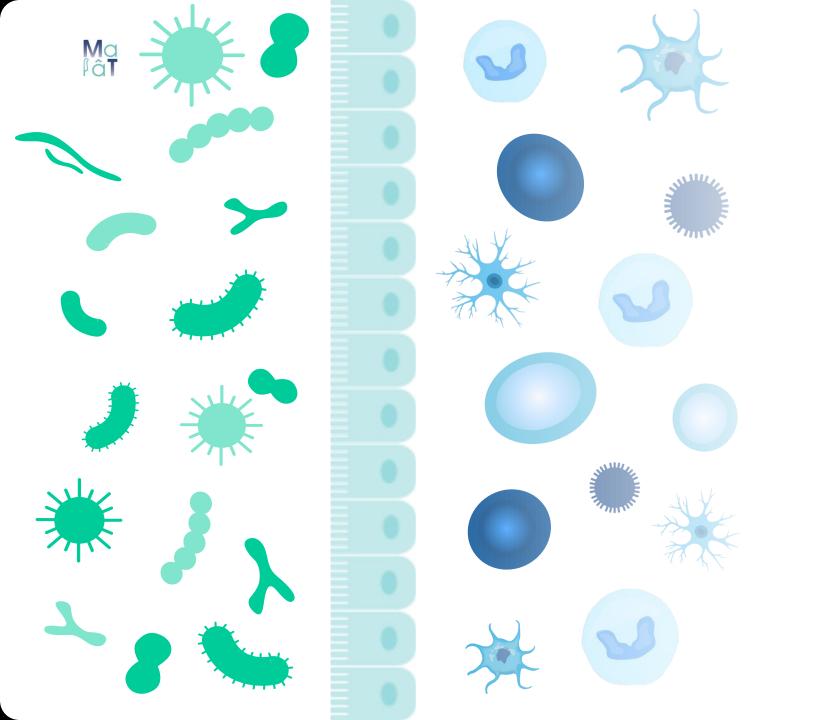
(Data published in a poster at MNDA, 35th International symposium on ALS/MND)



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

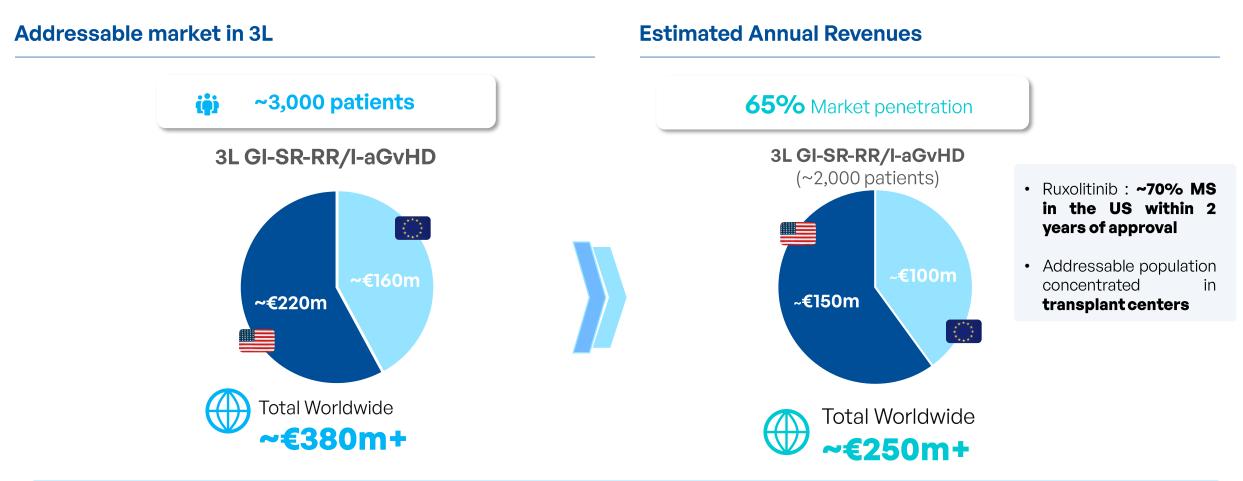
() MET-C • ICI and more





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

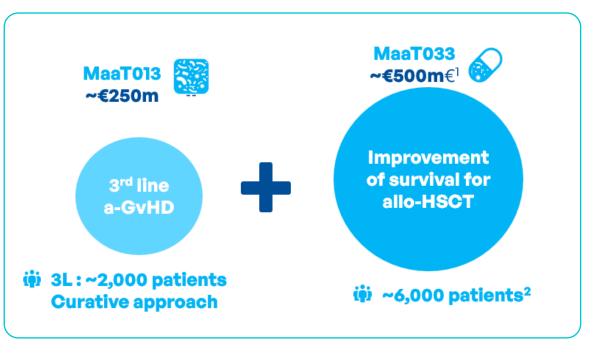
#### **Unique Franchise Opportunity**

- 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

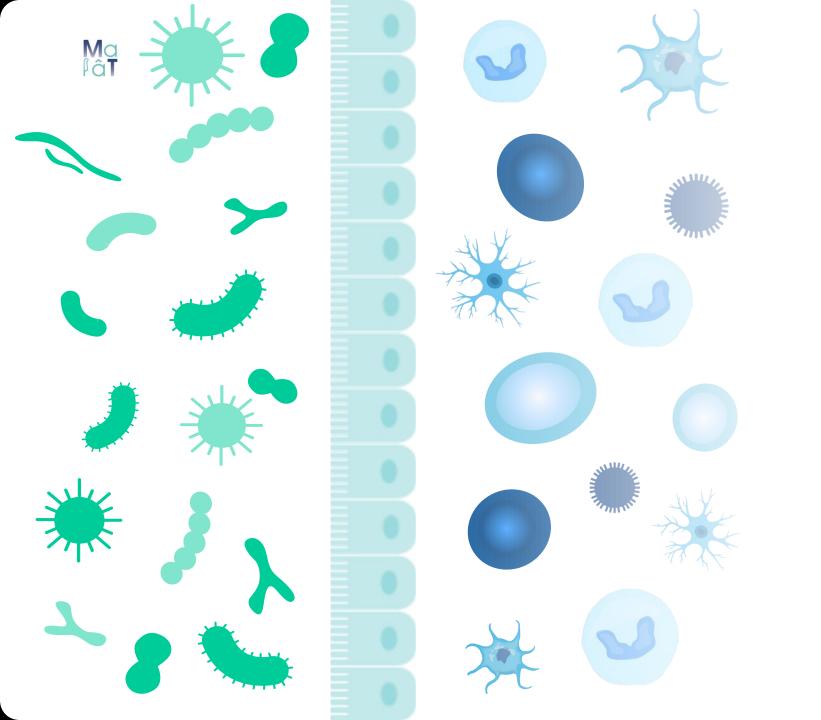
Significant potential to leverage partner's expertise in hematology, rare diseases, or hospital commercial operations.

#### A very meaningful market opportunity





<sup>1</sup>PYS EU5, US;<sup>2</sup> Per year



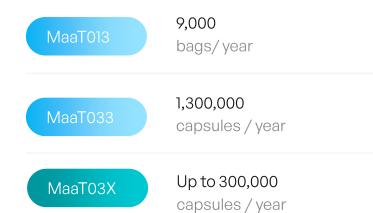
End-to-End In-house cGMP Manufacturing Capabilities

## 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





## 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

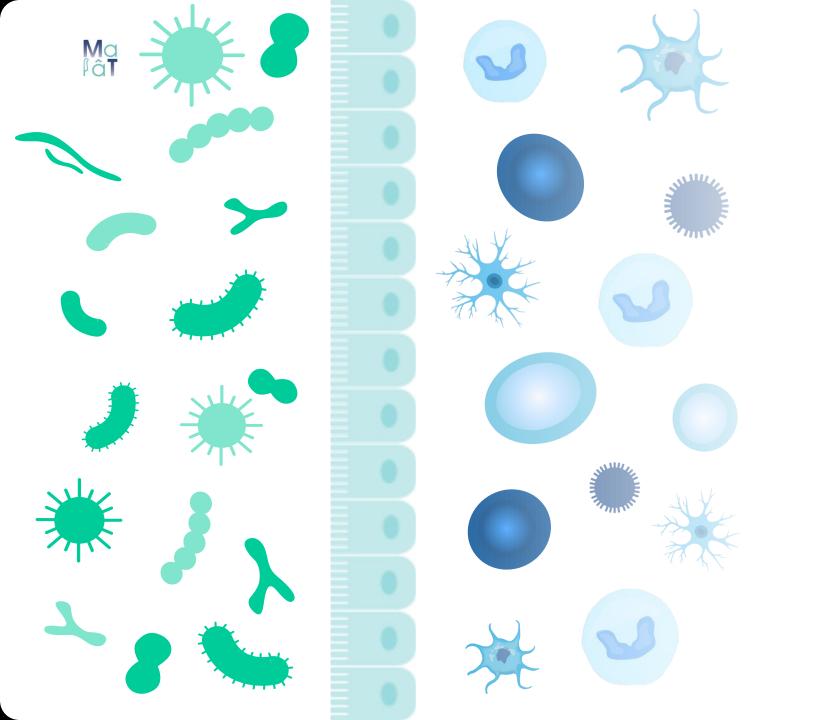


Currently used at 10% capacity **Scalable up to commercial capacity** 

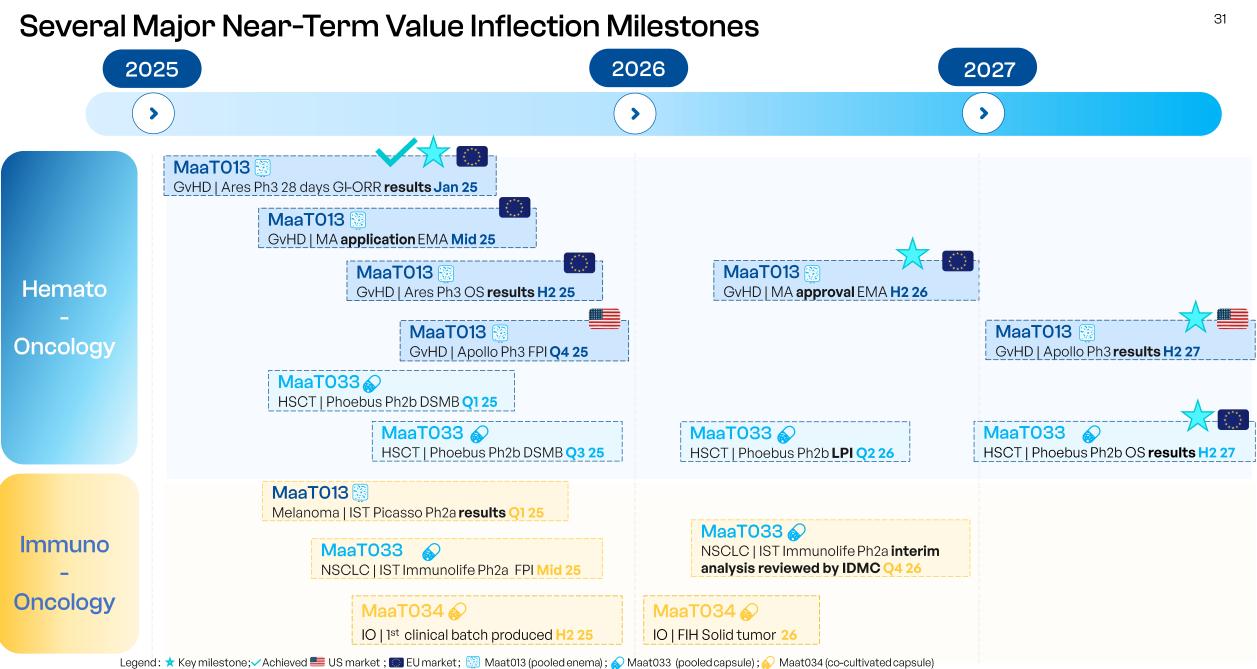


Partnership with





# Newsflow & Funding Opportunities



## Opportunities to fund the Company's development

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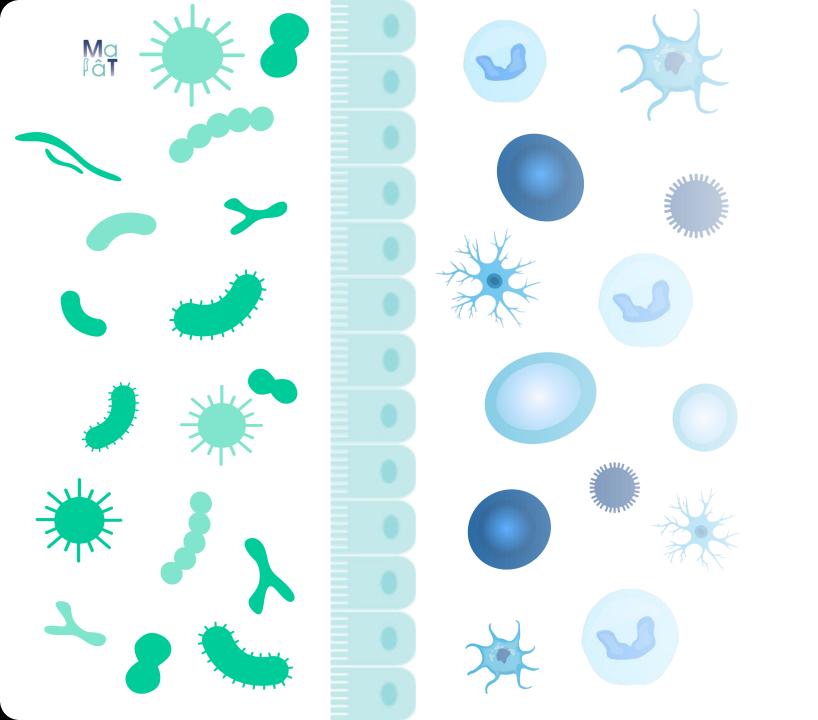
Cash position of €27m as of September 30,2024

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

