

MaaT Pharma

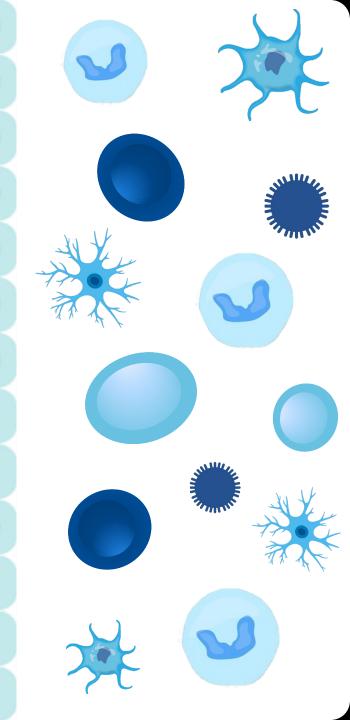
## Boosting Survival Through Innovative Immune Modulation

December 2025









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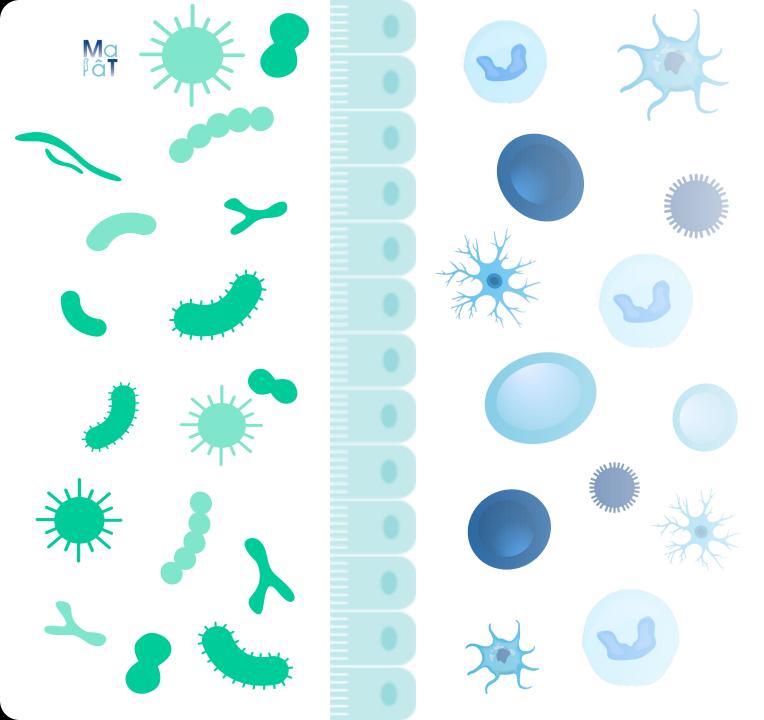
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## **Company Overview**

#### MaaTO13 (Xervyteg<sup>®</sup>) in aGvHD: Achieved All Endpoints of Phase 3 Study Registration in Europe Will Spearhead Microbiome Therapies in Oncology



### Xervyteg<sup>®</sup> Moving Closer to Commercial Launch

- Final results of pivotal Phase 3

  confirmed global clinical benefit with endpoints achieved (GI-ORR of 62% & 1Y OS of 54%)- Oral presentation at ASH 2025<sup>1</sup>
- MAA under review in Europe with EMA
- Commercialization Partnership With Clinigen in acute Graft-versus Host Disease in Europe



## **Multi-Assets Platform Focused on Oncology**

 Shared foundation to develop full-ecosystem, donor-derived and Al-powered co-cultured candidates

- 2 clinical and 1 preclinical assets
- Largest European cGMP production facilities for Microbiome Ecosystem
  Therapies<sup>TM</sup>







### Financial Overview

- Cash position of €22.4m as of September 30, 2025
- Cash runway to August 2026, including the October'25 Tranche A of EIB of 3.5m€, the November'25 capital increase of €8.7m and the expected Tranche B of €6.0m of the EIB
- Exploring additional funding options (non dilutive and/or dilutive) for future developments

**Dysbiosis & disease** 

Reduction of microbial metabolites

Associated with multiple conditions

Loss of microbial diversity

Increase in pathogens

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

hanced Survival Outcomes in Multiple Settings

Expected benefits

## diversity microbiota functional P production Restoration

Resolution of aGvHD

**Improved** 

survival in

Allo-HSCT

Xervyteg® (MaaT013)



Control of inflammation and restoration of gut integrity

Smith PM et al, Science 2013; Sun M et al, Nat Commun 2018; Gaudier E et al, AJPGLP 2004; Furusawa Y et al, Nature 2013; Arpaia N et al, Nature 2013; Mathewson ND et al, Nat Immunol 2016



MaaT033

Reduction of transplant-related complications

Jeng RR et al, Biol Blood Marrow Transplant 2005; Taur Y et al, Blood J Am Soc Hematol 2014



**)** MaaT034

response to ICI

**Optimization of anti-tumor immunity** 

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







Xervyteg<sup>®</sup>



MaaT033

PROPRIETARY POOLING APPROACH



Pooled → Maximized microbiota

(450 OTU ± 3%)

MaaT033

#### **Co-cultured Ecosystem**

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



MaaT034



MaaT03X

#### Master bank co-culture Working Bank cGMP proprietary process Unlimited Co-Culture Scaling

Original microbial ecosystem

#### **Integrated Production**

Leading capabilities in full ecosystem microbiome drug production





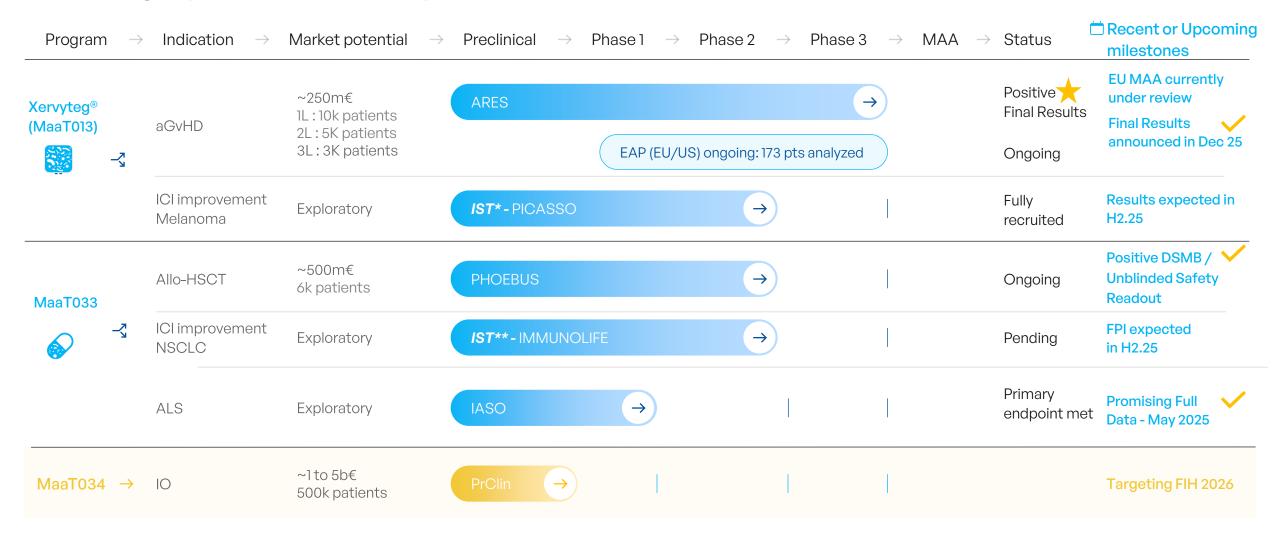
Capacity: ~11,000 treatable patients per year



Europe's Largest Facility Dedicated to Microbiome Ecosystem Therapies<sup>TM</sup> powers our integrated production of a premier portfolio of native and co-cultured treatments—designed for seamless scalability

MET-C product

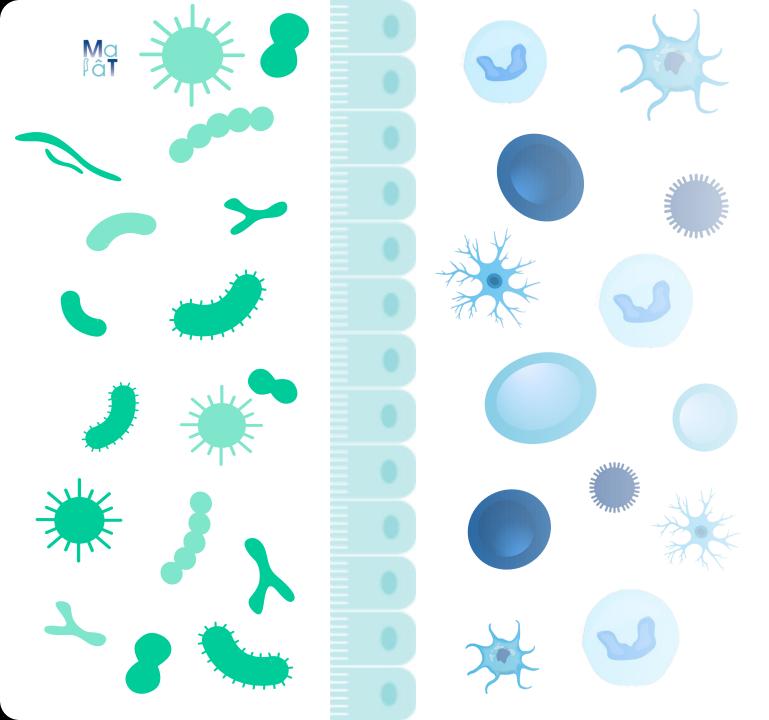
#### A Strong Pipeline With Multiple Value Inflection Milestones and a Close-to-Market Asset



aGvHD: acute Graft versus Host Disease; IO: Immuno-Oncology; PoC: Proof of Concept; Allo-HSCT: Allogeneic 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

<sup>\*</sup> R&D partners include AP-HP, Gustave Roussy

<sup>\*\*</sup> IGustave Roussy, INSERM, Université Paris-Saclay, Bioaster, INRAe, IHU Méditerranée Infection



## Xervyteg® in aGvHD



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

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







- Observed in approximately 50% Allo-HSCT Patients
- GvHD is characterized by intestinal dysbiosis associated with higher mortality<sup>2</sup>



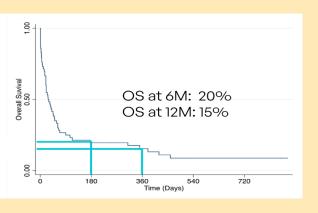
> 11,000 GvHD Patients / year

#### Treatment Paradigm

- 1st Line treatment: Corticosteroids
- 2<sup>nd</sup> Line treatment: Ruxolitinib approved for SR-aGvHD
- 3<sup>rd</sup> Line treatment: **No approved therapy**
- Off label Best Available Therapies (BAT) have shown limited benefit



1 year mortality in 3L+



median survival of **28 days** and 15% OS at 1-year

Around 3,000 per year EU/US

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#### Xervyteg<sup>®</sup>: A Standardized, Pooled, Allogeneic Microbiota Medicine Currently Under Review by the EMA



Orphan Drug Designation from **FDA** and **EMA** 



#### **Characteristics:** Pooled allogeneic faecal microbiota

- Full ecosystem
- High-diversity (including richness)
- Large choice of species to patients → Enhance engraftment
- Each drug product bag must contain not less than  $1.35 \times 10^{11}$  viable bacteria per dose



**Clinical Signals** 

- Over 330 patients treated to date
- Remarkable efficacy results
- Positive benefit/risk profile



PROPRIETARY POOLING **APPROACH** 



Xervyteg® (MaaT013)

#### Pooled microbiota

- → Maximized richness
- → Standardized (450 OTU ± 3%)



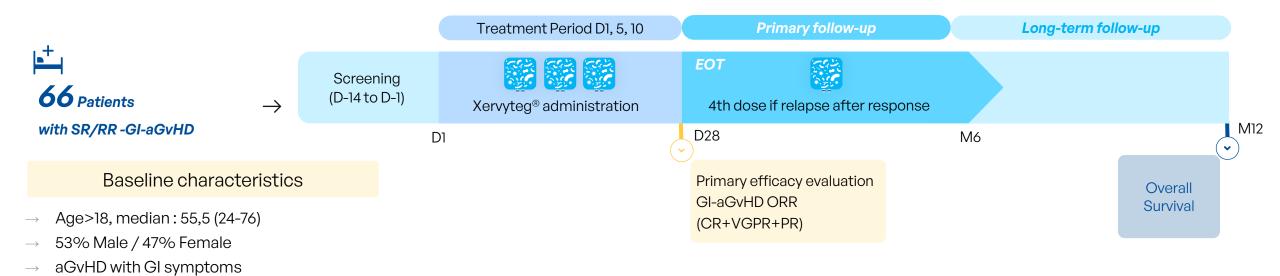




## ARES: a Pivotal Phase 3 Trial Exploring Xervyteg® in Third-Line aGvHD Following Steroid and Ruxolitinib Failure



Milestones: Topline results announced January 8th, 2025 / EMA MAA filed on June 2nd, 2025 / Final results announced on December 8th, 2025







91% are Grade III-IV

2L 100% Ruxolitinib-refractory

#### **Dec. 25 Final Results confirming:**

1L 86% Steroid-refractory / 14% -dependent

- → Remarkable efficacy results
- → Positive benefit/risk profile



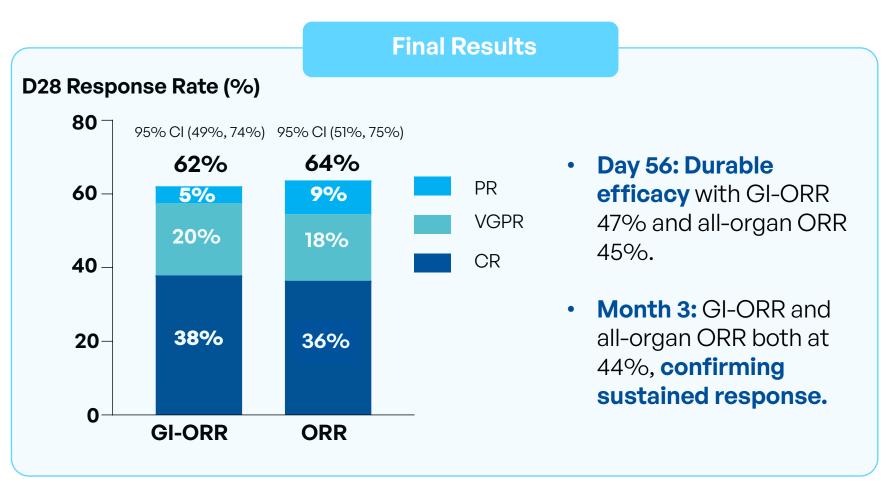


Market potential: ~250 m€ EU & US No Competitor in 3L





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



These results confirm that Xervyteg® offers a durable clinical benefit for patients with GI-aGvHD. Achieving a 62% GI-ORR at Day 28, maintaining responses over time, and reaching a 54% oneyear overall survival represent a meaningful step forward in addressing this critical unmet need.

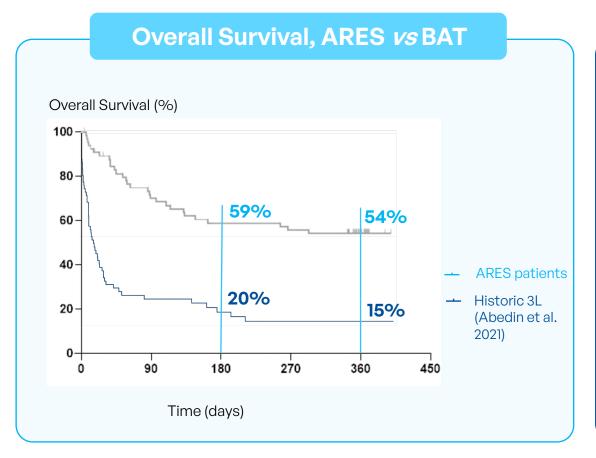
Prof. Malard, MD, hematology professor at Saint-Antoine Hospital and Sorbonne University, lead investigator for the Phase 3 ARES trial



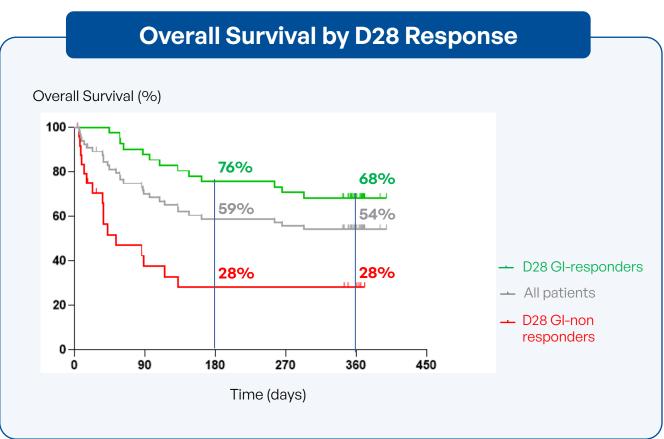
The study met all endpoints, and the final results show **durable** responses Xervyteg® with a significant gastrointestinal overall response rate (p < 0.0001).

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#### ARES: Unprecedented Overall Survival Rate Compared to Historical Data with **Best Available Therapy (BAT)**



Quick action



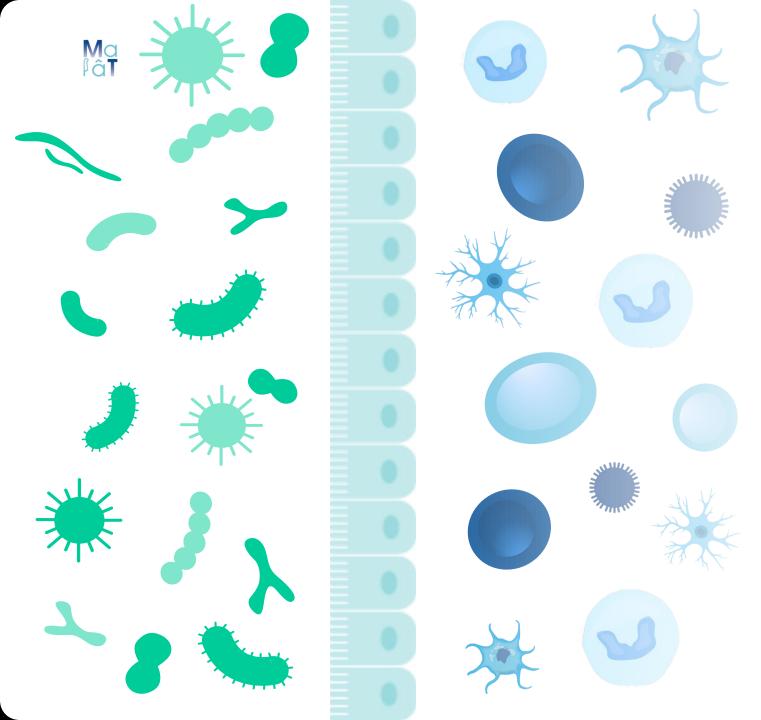
Xervyteg® demonstrates response-driven prolonged survival, far exceeding expected third-line aGvHD, with 54% overall survival rate at 1 year compared to 15% survival in historical published data.



**Key Takeaways** 

### Xervyteg®, a potential triple first

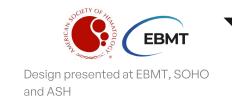
- 1st Microbiota Therapy in Europe (submission)
- 1st Microbiota Therapy in Oncology Worldwide
- 1st Treatment for third-line GI-aGvHD



## MaaT033 in allo-HSCT

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





#### Largest Microbiome RCT trial in oncology

- Multicenter Randomized Control Trial
- 56 sites / 6 countries

- Primary endpoint: 1y-OS
- Results: exp. Q4-2027
- Dec 2024: 80 patients (LPI target date: mid-26)



**Ongoing Phase 2b PHOEBUS** designed to be pivotal



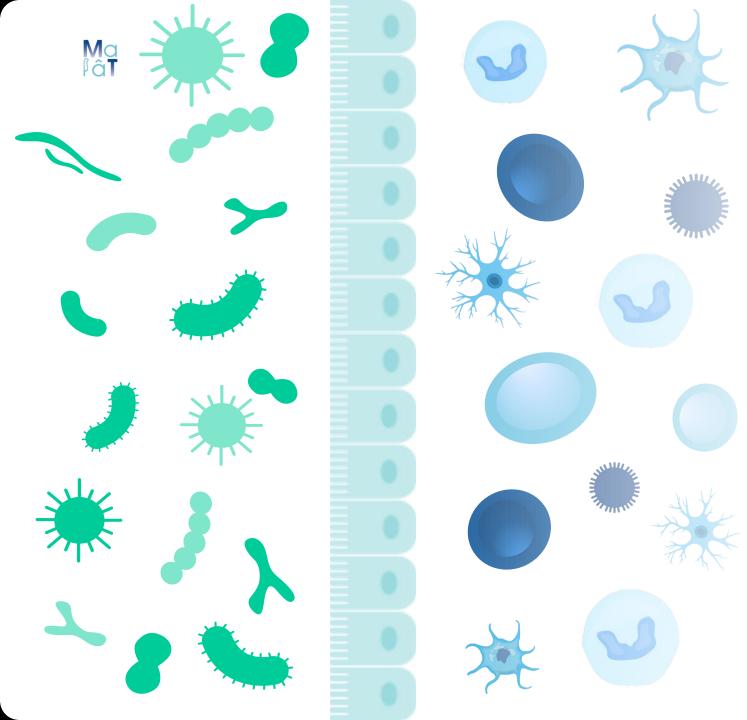
October 2025: Positive **Unblinded Interim Analysis by** DSMB (n=120) - Trial To **Continue as Planned** 



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



~ 6k patients per year



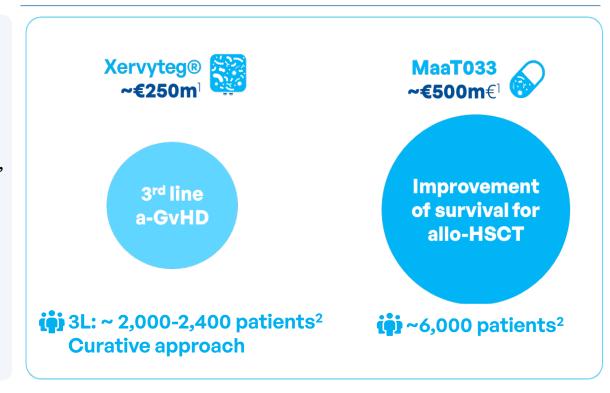
# Commercial And Distribution Strategy in Hemato-Oncology

#### Leadership in Hemato-Oncology Across the Full Care Continuum of HSCT

#### **Unique Value Proposition**

- Unique immunosuppressant-sparing, microbiome-based treatment option in aGvHD
- Well defined target population for both products
- Prescribers are concentrated on limited number of centers, part of them already using Xervyteg® in the EAP
- Proven efficacy and safety with potential to expand to other dysbiosis-associated hematological malignancies (e.g., CAR-T)
- Multiple short-term value catalysts within next few months.

#### **A Significant Market Opportunity**

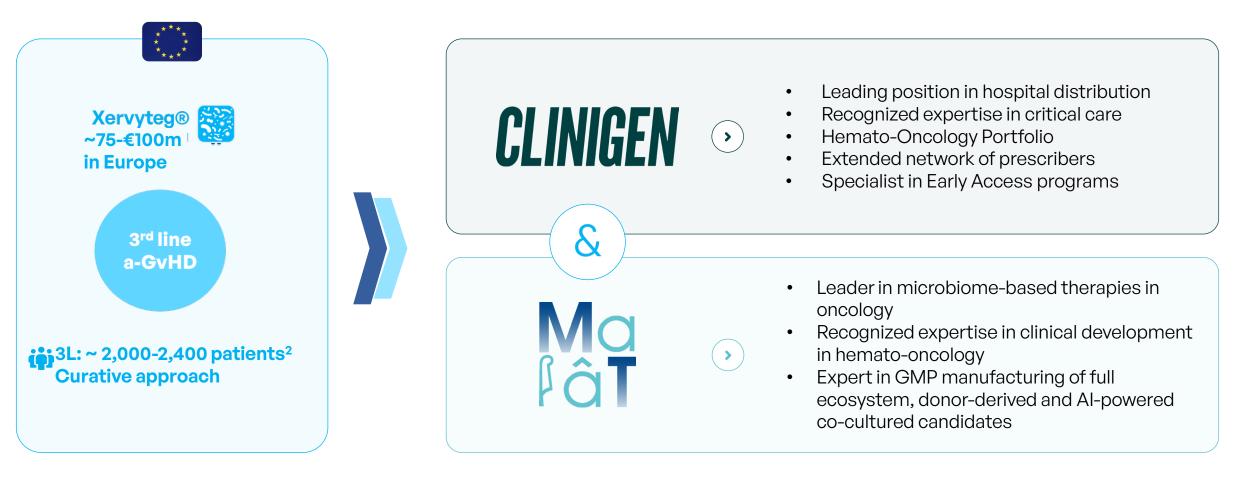


Significant opportunity to leverage partner's expertise in hematology, rare diseases, and hospital commercial operations.



MaaT Pharma

#### Licensing Late Stage Asset Xervyteg® to Clinigen for Commercialization in Europe



This commercial and distribution agreement in **Europe** is a **benchmark** for future agreements in other regions such as **Asia, Middle East and beyond**, for both **Xervyteg®(MaaT013)** and **MaaT033** 

#### Synergy with Purpose: Growth Driven by Patient-Centric Collaboration



#### **Commercialization**

- MaaT Pharma will manufacture and supply the product to Clinigen. If approved, MaaT Pharma to hold the Marketing Authorization.
- Leveraging on its large footprint and solid knowledge of Hematooncology, Clinigen will manage commercialization i.e. marketing, promotion and distribution of Xervyteg<sup>®</sup>.



**EU27 +** Iceland, Norway, Liechtenstein and the United Kingdom





#### **Early Access Program**

Clinigen will start managing the Early Access Program in Europe, building on MaaT Pharma long standing experience.
This will allow MaaT Pharma team to focus on core expertise such as Clinical/Regulatory activities.





Market access
Early Access Program
KOL engagement
Large hospital networks







Discovery
Clinical development
Regulatory milestones
Industrial scale-up

#### Bringing Xervyteg® to Market: Financial terms of the Commercial Partnership for Europe

Financial Terms

Upfront payment

10.5M€

MAA milestone

12M€

Sales milestones

Up to 6M€

Royalties on net sales

**Mid-thirties** 

**Drug Supply** 

**Set Cost Terms** 

European Market for Xervyteg®

Total Adressable Population in 3L aGvHD\*

Ca. **1.900** 

Patients Treated at peak\*

1.200 - 1.600

Expected Yearly Peak Sales\*

between **75-100M€** 

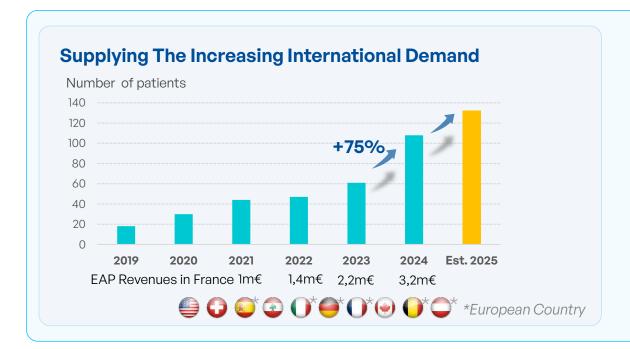
Potential revenues generation

H2 2026 If approved

\*MaaT Pharma's estimates

**Extending cash runway** through **non-dilutive upfront payment** while securing sustained funding through milestone payments and recurring revenues.

#### Early Access Program in Europe will Transition to Clinigen



#### **Clinical Outcomes**

- 252 requests and 173 GvHD patients analyzed as of October 2024 and presented at EHA 2025:
  - Efficacy (All lines) = GI-ORR at D28: 53%; 1Y OS: 48%
  - Efficacy (3L) = GI-ORR at D28: **57%**; IY OS: **51%** consistent with ARES data:
  - ARES Data = GI-ORR at D28: **62%**; ly OS: **54%**
  - Safety = Favorable B/R ratio
- Product positioning in third-line (3L) aGvHD



#### Today with MaaT Pharma, Tomorrow with Clinigen



#### **Today - Supply chain & Manufacturing**

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



#### **Tomorrow with Clinigen in Europe**

- Leverage the infrastructure of Clinigen, in Europe, from day one.
- Boost adoption and expand patient access.



## Largest European cGMP Manufacturing Facility for Microbiome Ecosystem Therapies<sup>TM</sup>



Xervyteg®

9,000 products/year; 3,000 patients/year

MaaT033

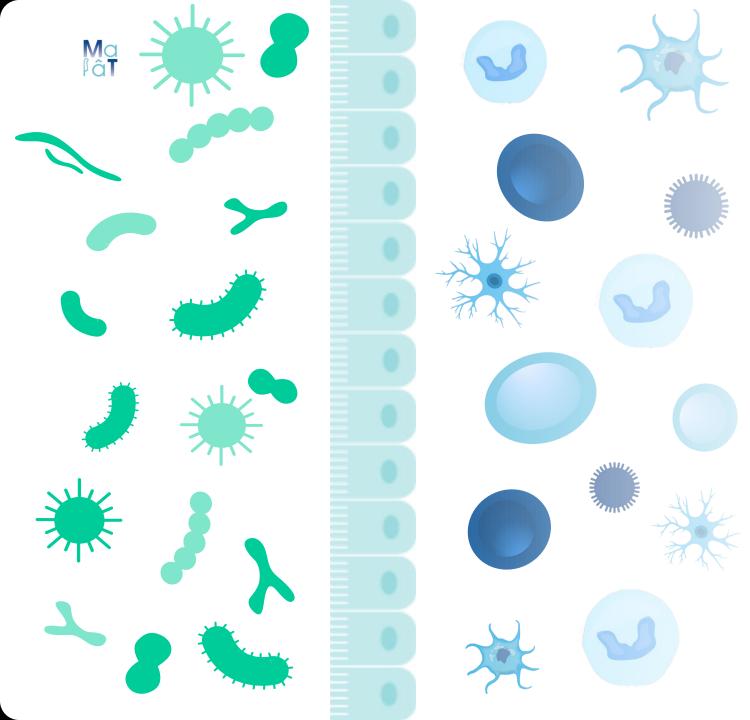
1,300,000 capsules/year; 6,000 patients / year

MaaT03X

Up to 300,000 capsules/year

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





## Future Growth Drivers in Immuno-Oncology

#### 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

**⊘** 3/10

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

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



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



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

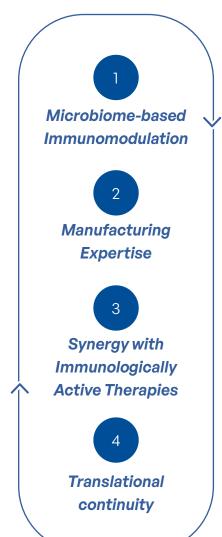


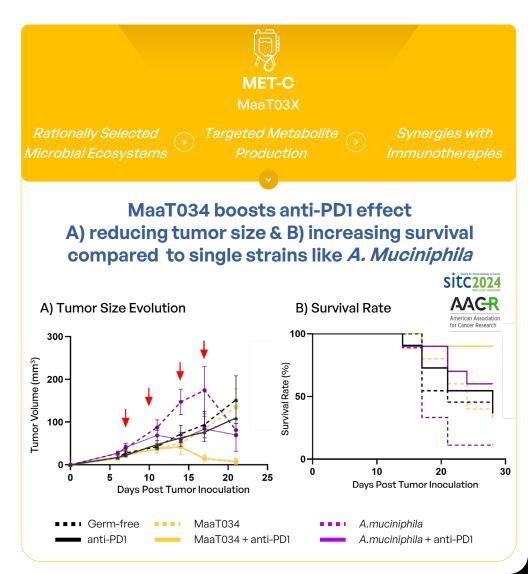
PICASSO studying Xervyteg®: 1st multicenter **RCT 70 pts rand 1:1** 

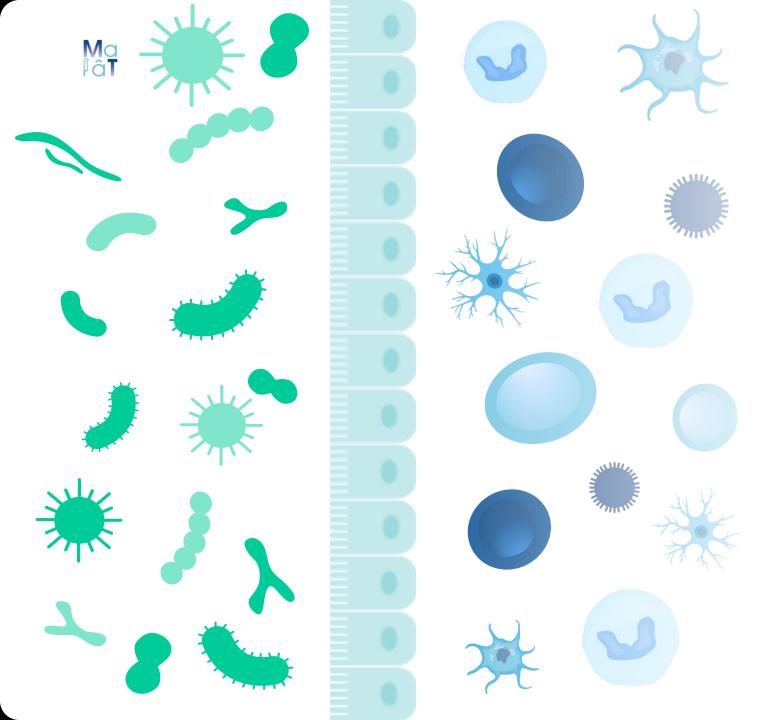
#### From Proof to Platform: An Integrated IO Strategy

Coordinated development path leveraging on proven safety profile of Xervyteg® while optimizing MaaT034



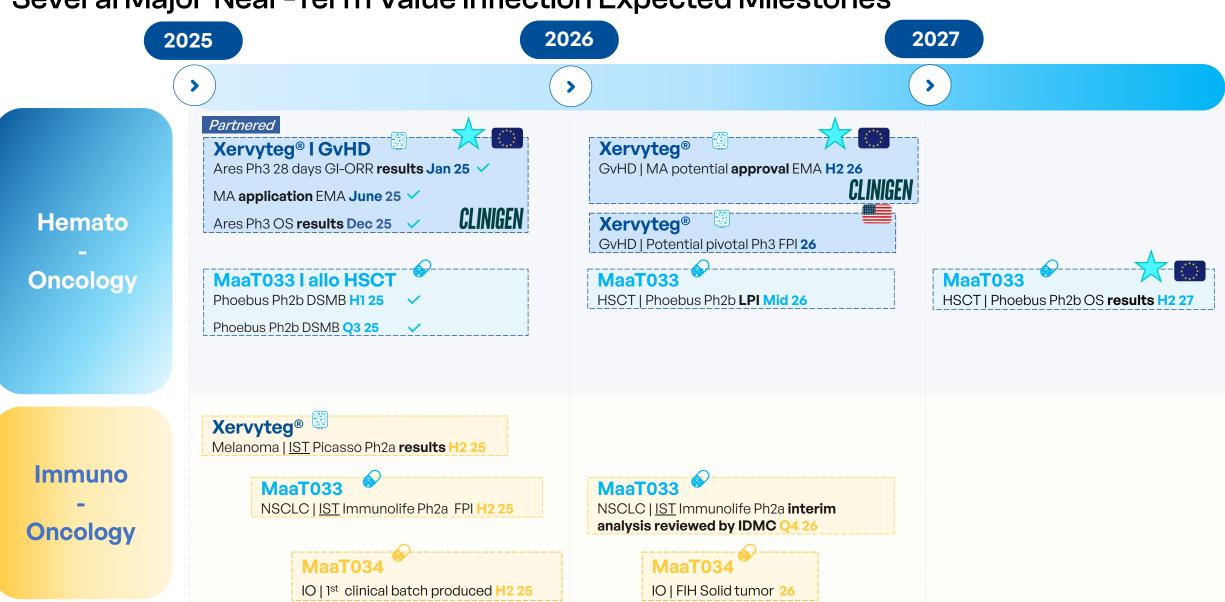






## Looking Ahead & Key Takeaways

#### Several Major Near-Term Value Inflection Expected Milestones



#### Key takeaways on MaaT Pharma

#### **Progress of the Pipeline**

- Leadership in Hemato-Oncology through immune modulation with microbiome-derived therapies across all treatment stages
- Exploring Immuno-Oncology preclinically with MaaT034 with strong anti-tumor activity coupled with ICI and Clinically with exploratory Investigator Sponsor trials (PICASSO with Xervyteg® & Immunolife with MaaT033)

#### **Commercial and Distribution Strategy**

- Clinigen will manage commercialization, marketing & promotion of Xervyteg®, MaaT Pharma will manufacture and supply the product and, if approved, will hold the Marketing Authorization
- MaaT033, with greater market potential, is positioned for similar deals, pending data maturation to secure optimal terms

#### **Financial Figures**

- Cash position of €22.4m as of September 30, 2025
- Cash runway to August 2026, including the October'25 EIB Tranche A funding of 3.5m€, the November'25 capital increase of €8.7m & expected EIB Tranche B funding of €6.0m
- 37.5m€ loan from European Investment Bank (EIB) in four tranches (€3.5m for Tranche A, €6.0m for Tranche B, €8.0m for Tranche C, and €20.0m for Tranche D) subject to operational and financing conditions.
- > Exploring additional funding options (non dilutive and/or dilutive) for future developments

Leading the Field in MicrobiomeDriven Immune
Modulation

## Corporate Social Responsibility

MaaT Pharma is a leading, late-stage clinical Company committed to advancing gut microbiome science to deliver safe, sustainable, and innovative therapies that modulate the immune system and improve outcomes for cancer patients.







Patients are the priority. MaaT Pharma is committed to patients and to the protection of human health by respecting the environment, valuing its employees, and ensuring good governance practices.

MaaT Pharma's core values are guided by the following four principles:

- Innovate and raise awareness to deliver better care,
- Foster employee growth within a peopleoriented ecosystem,
- Place ethics and transparency at the core of the Company's strategy,
- → Control and measure the Company's environmental impact.

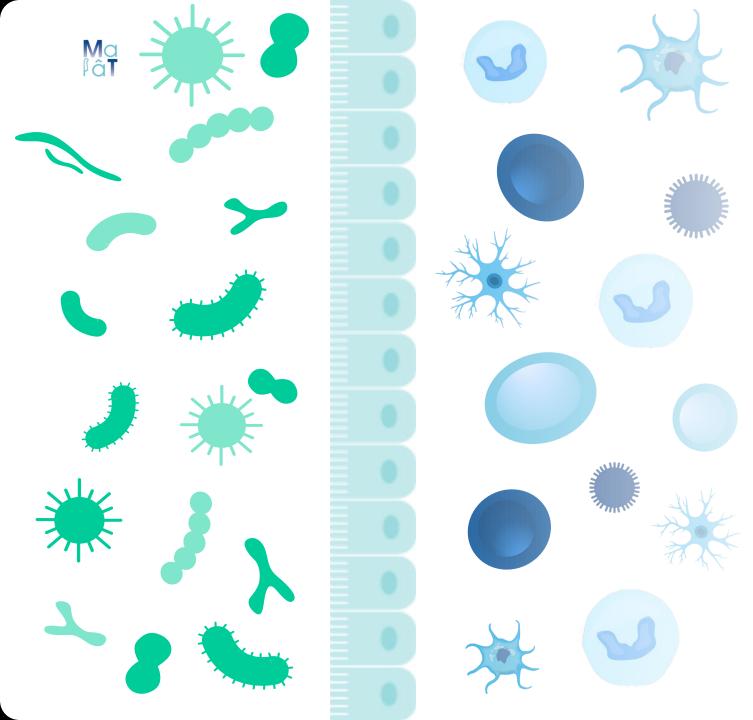
#### 2024 CSR indicators

Social	
37 y-o	is the average age of permanent employees
17	permanent employees under 30 years old (as of 12/31/24)
94%	Training Plan Completion Rate

Carbon footprint
Energy consumption per employees on site

Societal	
81%	of operating expenses related to R&D as a proportion of total operating
290	expenses  public interventions to increase awareness on microbiome

Governance		
43%	of women in the Board of directors	
<b>57</b> %	of independents in the Board of directors	
55%	of women in the Executive team	



## Thank you



