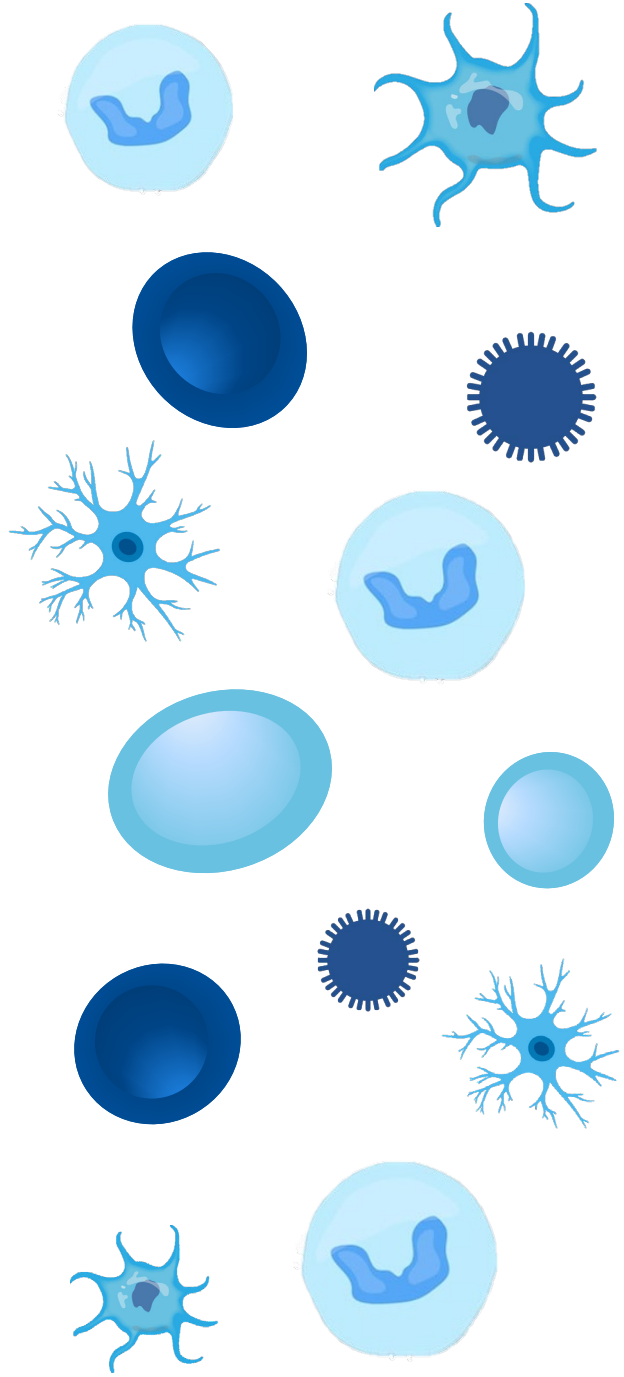
MaaT Pharma

# Boosting Survival Through Innovative Immune Modulation

June 2025

MAAT LISTED EURONEXT

ELIGIBLE PEA PME



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# Management Team

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**Eric Soyer**

Chief Financial Officer

**Gianfranco Pittari, MD, PhD**

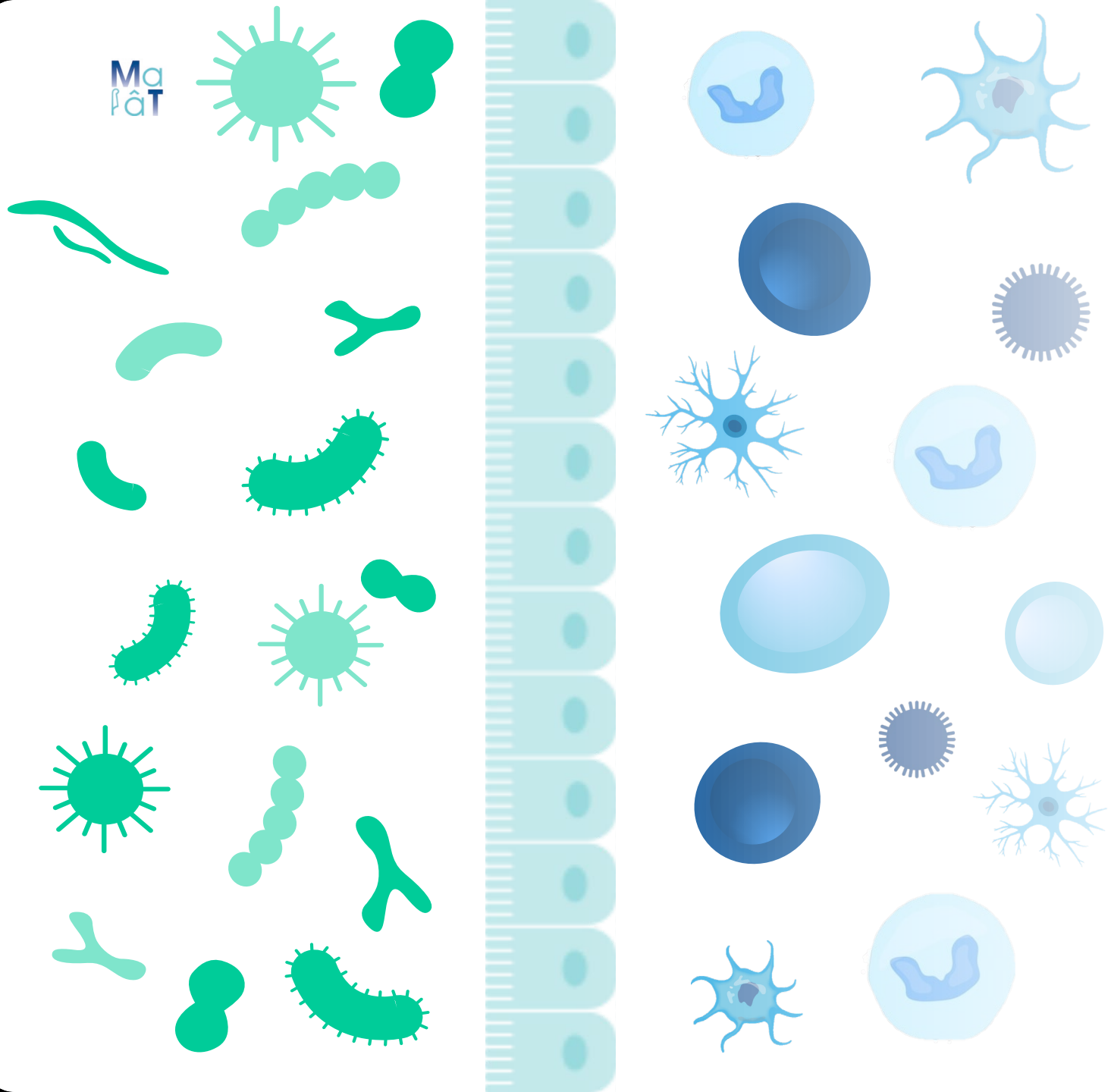
Chief Medical Officer

**Carole Schwintner, PhD**

Chief Technology Officer

**Jonathan Chriqui, PharmD**

Chief Business Officer



# Company Overview

# Xervyteg® 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 Xervyteg®'s potential to overcome the short-term mortality of third-line GI-aGvHD[1,2]
- Company submitted **MAA in Europe on June 2nd, 2025**

## 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 Xervyteg® in GvHD and 500m€ for MaaT033 in allo-HSCT.
- **Cash position** of **24.4m€** as of March 31, 2025. **Post capital increase of €13m in March 2025, cash runway** extended into **October 2025**
- Exploring **additional funding options** for future developments, including non-dilutive such as partnerships and other non-dilutive sources

[1]Malard, ASH 2024 [2]Abedin et al. 2021

# Correcting Dysbiosis: a New Pillar in Oncology

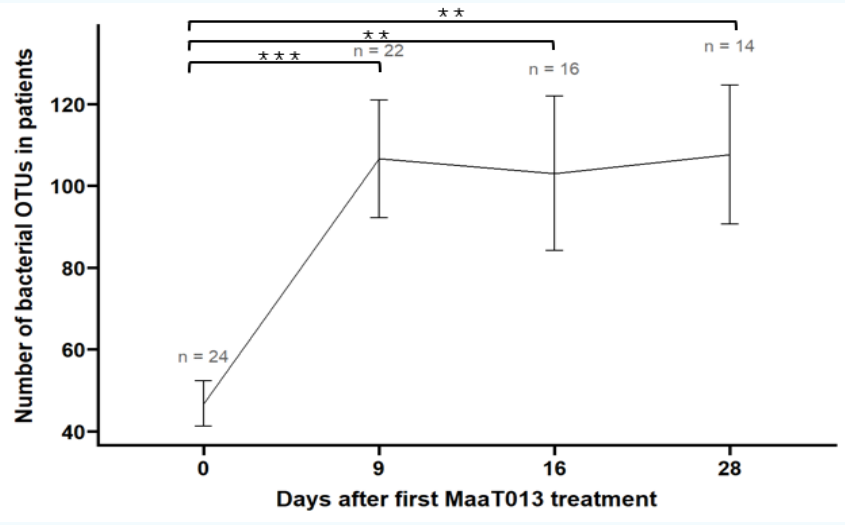
## Dysbiosis and disease

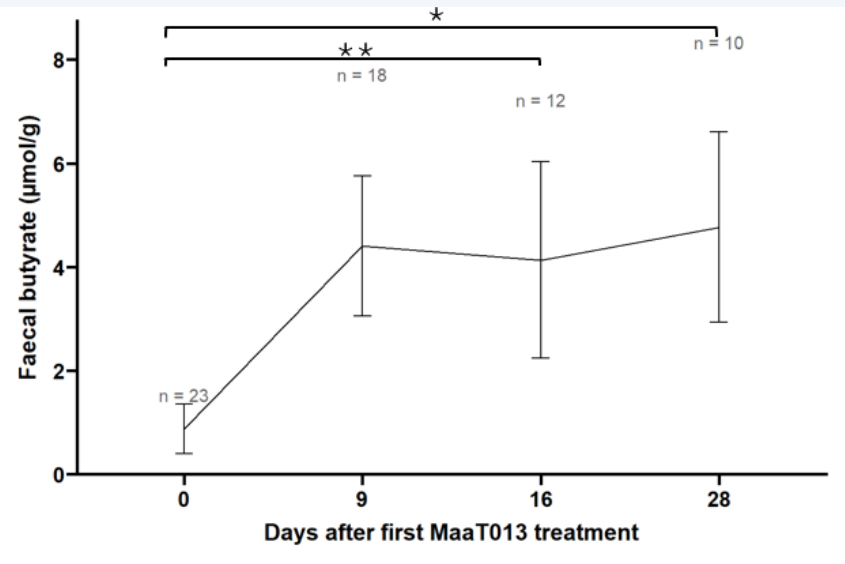
- Loss of microbial **diversity**
- Increase in **pathogens**
- Reduction of **microbial metabolites**
- Associated with **multiple conditions**

## 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**




Malard, F. *et al.* Pooled allogeneic faecal microbiota Xervyteg® 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

gut Print

## Native Ecosystem

**Driving near-term value with the donor-derived MET-N platform**

- Xervyteg®
- MaaT033

## Co-cultured Ecosystem

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

- MaaT034
- MaaT03X

## In-house Production

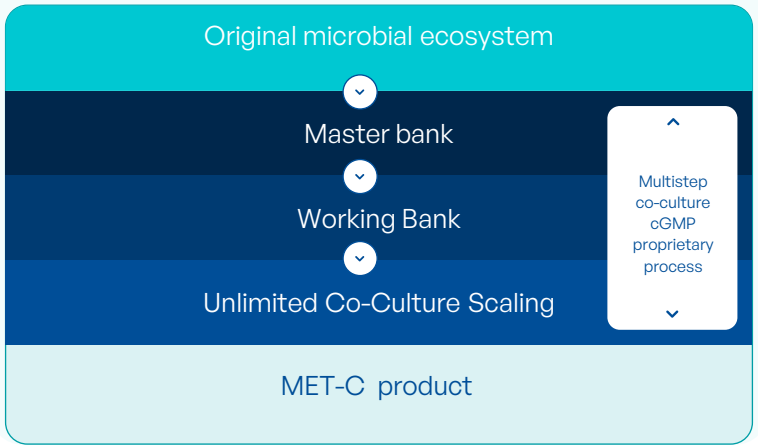
**Leading capabilities in full ecosystem microbiome drug production**

**Capacity: ~11,000 treatable patients per year**

**PROPRIETARY POOLING APPROACH**

Xervyteg® + 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 | Recent or Upcoming milestones |
|---|---|---|---|---|---|---|---|---|---|
| Xervyteg® | aGvHD | ~250m€<br>1L : 10k patients[2]<br>2L : 5K patients[2,3]<br>3L : 3K patients[2,3] | | ARES → | | | | Primary endpoint met ★ | EU MAA submitted in June 2025 ✓ |
| | | | | EAP (EU/US) ongoing: 173 pts treated | | | | Ongoing | Updated data at EHA 2025 Congress |
| | ICI improvement Melanoma | POC | | ***IST**** - PICASSO → | | | | Fully recruited | Results H2.25 |
| MaaT033 | Allo-HSCT | ~500m€<br>11k patients[2] | | PHOEBUS → | | | | Ongoing | Positive Unblinded Safety data Interim Analysis - April 2025 ✓ |
| | ICI improvement NSCLC | POC | | ***IST**** - IMMUNOLIFE → | | | | Pending | FPI expected in H2.25 |
| | ALS | Exploratory | | IASO → | | | | Primary endpoint met | Promising Full Data - May 2025 ✓ |
| MaaT034 → | IO | ~1 to 5b€[1]<br>500k patients | | PrClin → | | | | | Targeting FIH 2026 |

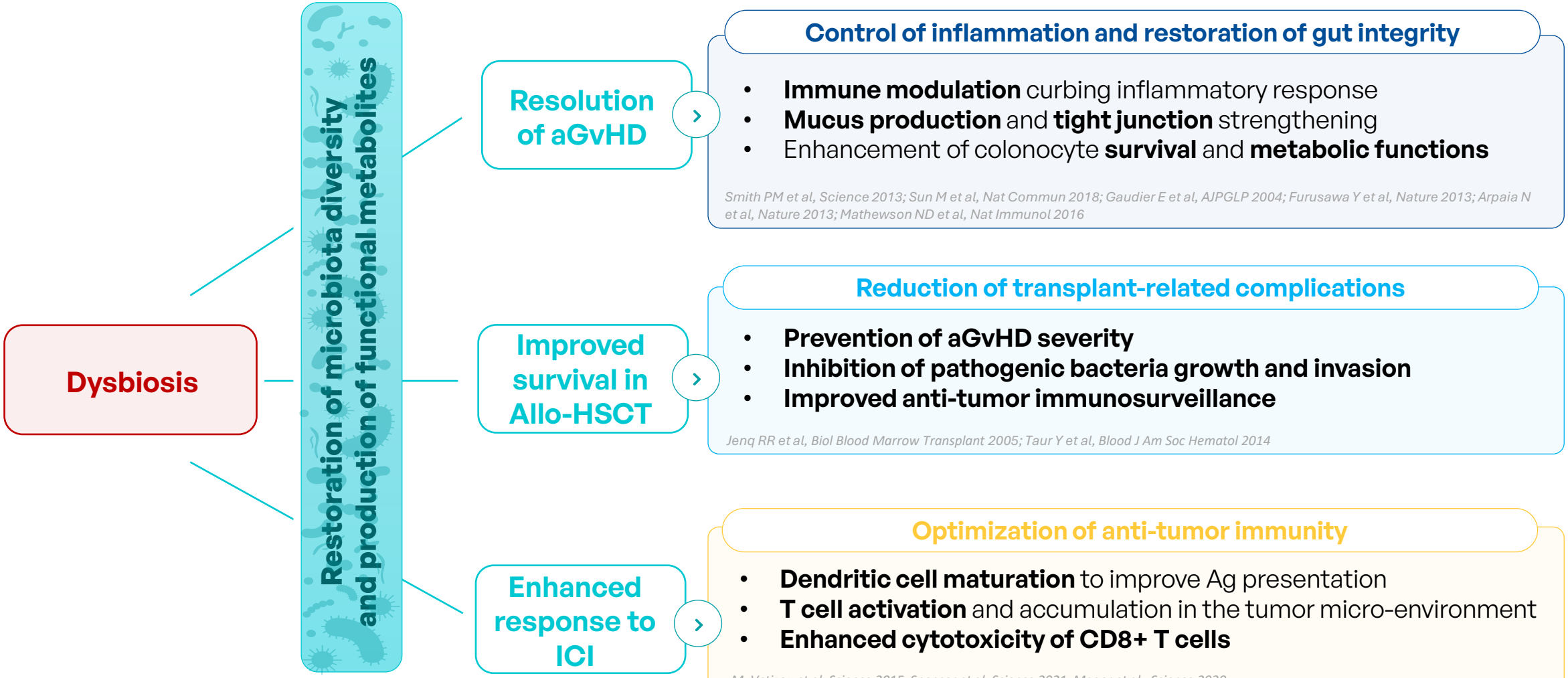
aGvHD: acute Graft versus Host Disease ; IO: Immuno-Oncology ; PoC: Proof of Concept; Allo-HSCT: Hematopoietic Stem Cell Transplantation ; ALS: Amyotrophic Lateral Sclerosis ; IST: Investigator Sponsored Trial; NSCLC: Non-small cell lung cancer - ICI PICASSO: ipilimumab (Yervoy®) and nivolumab (Opdivo®)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

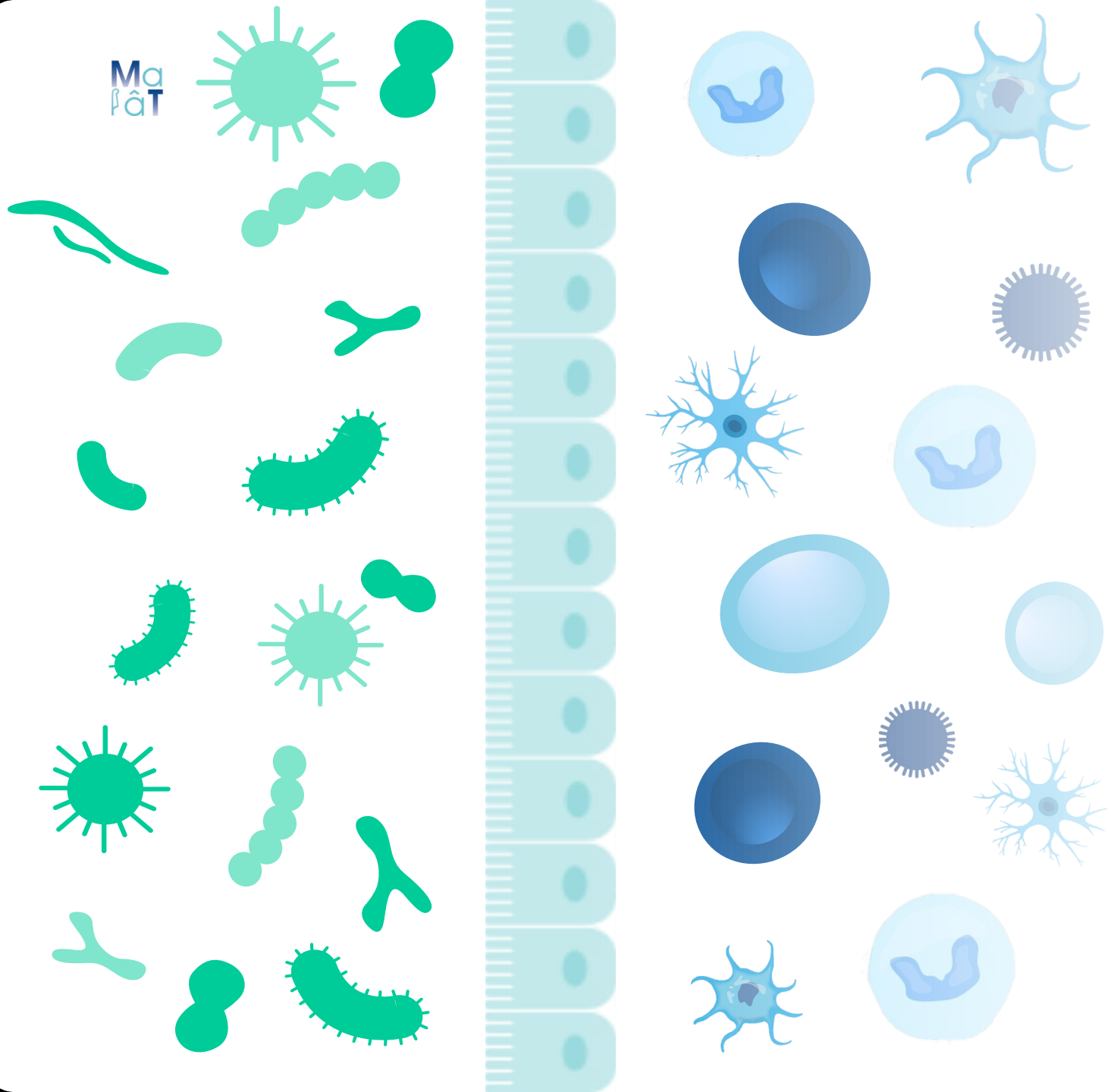
* R&D partners include AP-HP, Institut Gustave Roussy

** Institut Gustave Roussy, INSERM, Université Paris-Saclay, Bioaster, INRAe, IHU Méditerranée Infection

2025

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





# Xervyteg® in aGvHD

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

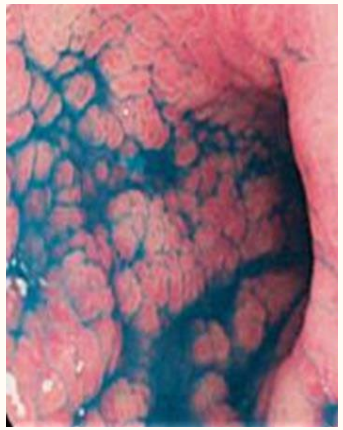
→ ***A significant complication following allogeneic hematopoietic stem cell transplantation (Allo-HSCT)***

→ ***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**

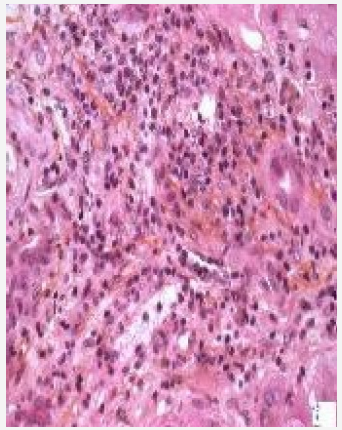
**Common clinical manifestations typically involve the gastrointestinal tract, the skin and the liver**

### GI GvHD



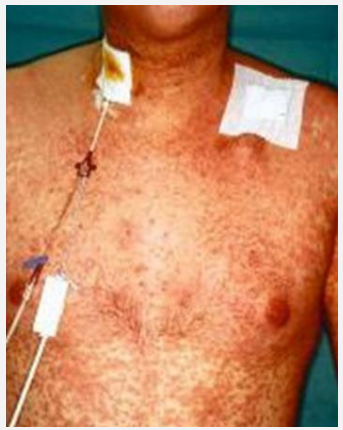
Severe diarrhea, abdominal pain

### Liver GvHD



Jaundice, liver dysfunction/failure

### Skin GvHD



Skin: Rash, itching

**~11,600**

GvHD Patients / year

**85%**

1 year mortality in 3L+[1]

→ ***Mortality is primarily linked to the involvement of the gastrointestinal tract***

[1]Abedin et al. 2021, BJHaem

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

## *Treatment Paradigm*

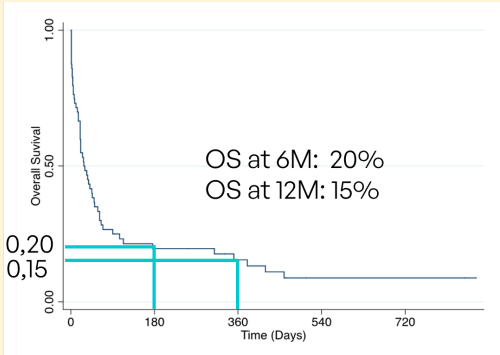
- Corticosteroids are the 1st line treatment, but approximately 50% of patients do not achieve a sustained response
- ruxolitinib is approved as 2nd line treatment for steroid-refractory aGvHD (FDA, 2019 & EMA, 2022)

**30%** of aGvHD patients ***eligible*** for subsequent or alternative treatment

***Approximately 3,000 per year EU/US***

## *Lack of effective therapy in 3rd 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***[1]

→ *GvHD is characterized by intestinal dysbiosis which is associated with higher mortality in hemato-oncology*[2]

→ *In the Early Access Program (EAP), Xervyteg® showed efficacy in aGvHD patients who failed 1 to 6 lines of systemic treatment*[3]

[1] Abedin et al., Br J Hematol 2021, [2] Peled et al., NEJM 2020; [3] Malard et al., ASH 2024

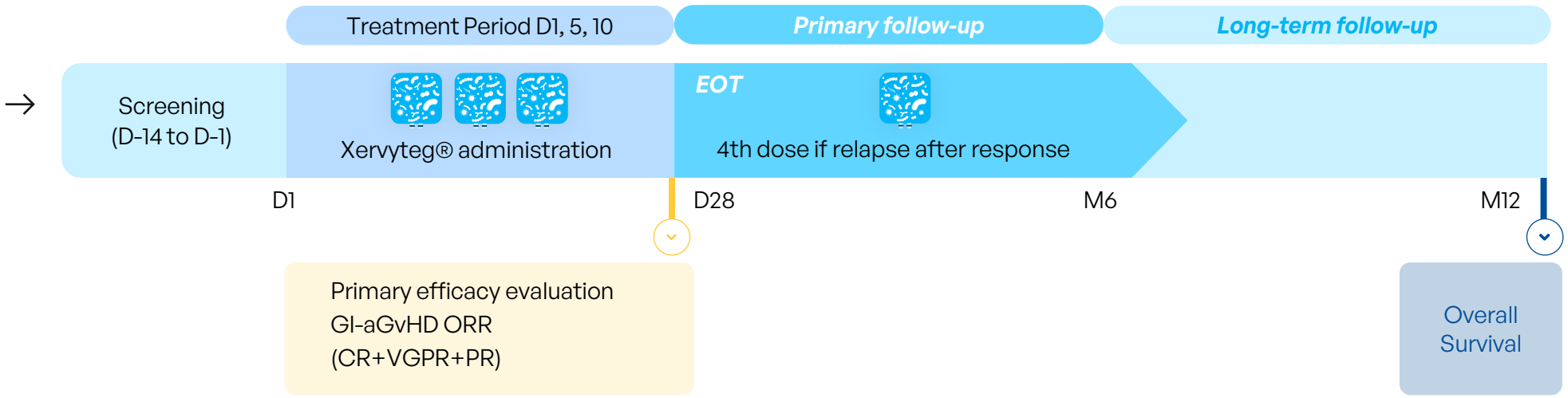
# ARES: a Pivotal Phase 3 Trial Exploring Xervyteg® in 3rd-Line aGvHD Following Steroid and Ruxolitinib Failure

***Milestones:* Topline results** announced ***January 8th 2025* / EMA MAA** filed on **June 2nd, 2025 /** OS expected by end of 2025

**66** ***Patients***
***with SR/RR -GI-aGvHD***

Inclusion criteria

- → Refractory to 1L corticosteroids
- → Refractory or intolerant to 2L ruxolitinib
- → aGvHD with GI symptoms
- → Allo-HSCT
- → Age > 18




**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 Xervyteg® (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%) |
| | 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%)** |

*MAGIC : Mount Sinai Acute GVHD International Consortium

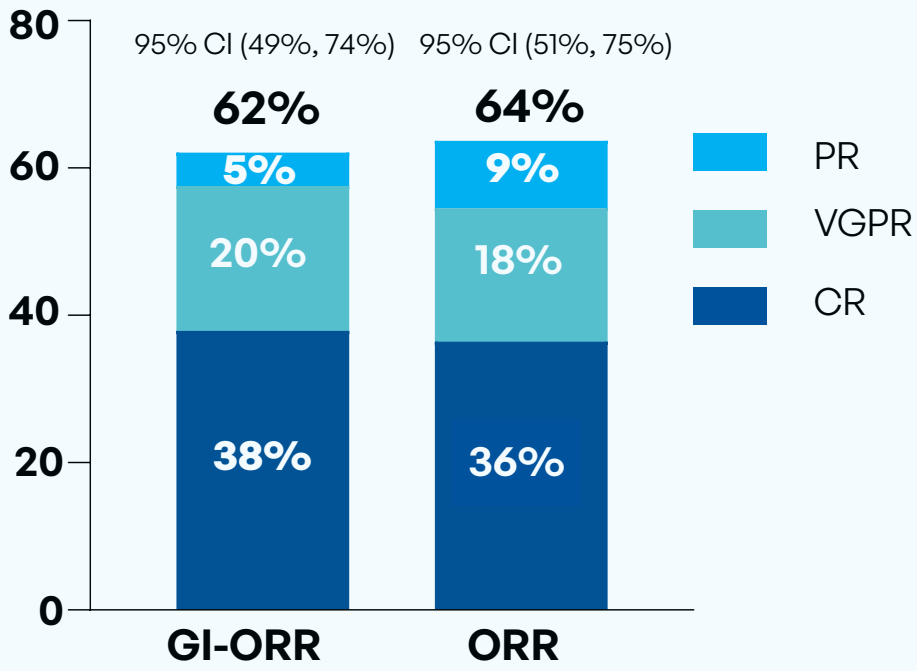
**Patients with severe aGvHD**

**91% are Grade III-IV** | **100% are ruxolitinib refactory**

# ARES: Strong Response to Xervyteg® 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

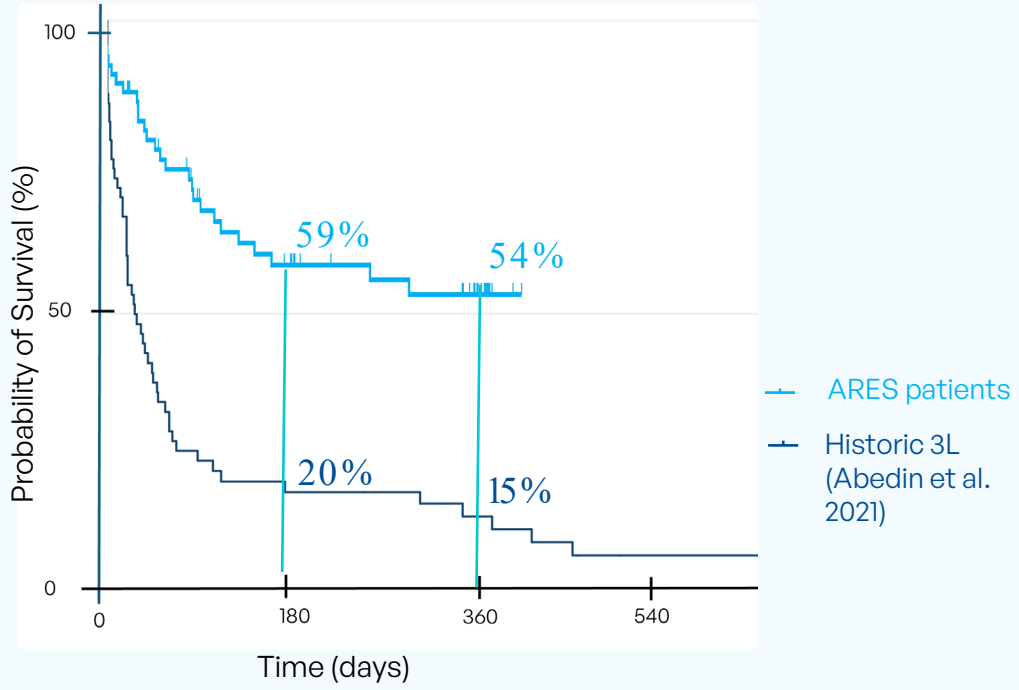
> *These outcomes underscore the curative role of microbiota-based therapies in achieving durable responses leading to prolonged survival. As [Xervyteg®(MaaT013)] gains adoption in Europe, it has the potential to redefine care standards for patients facing this life-threatening complication.*

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

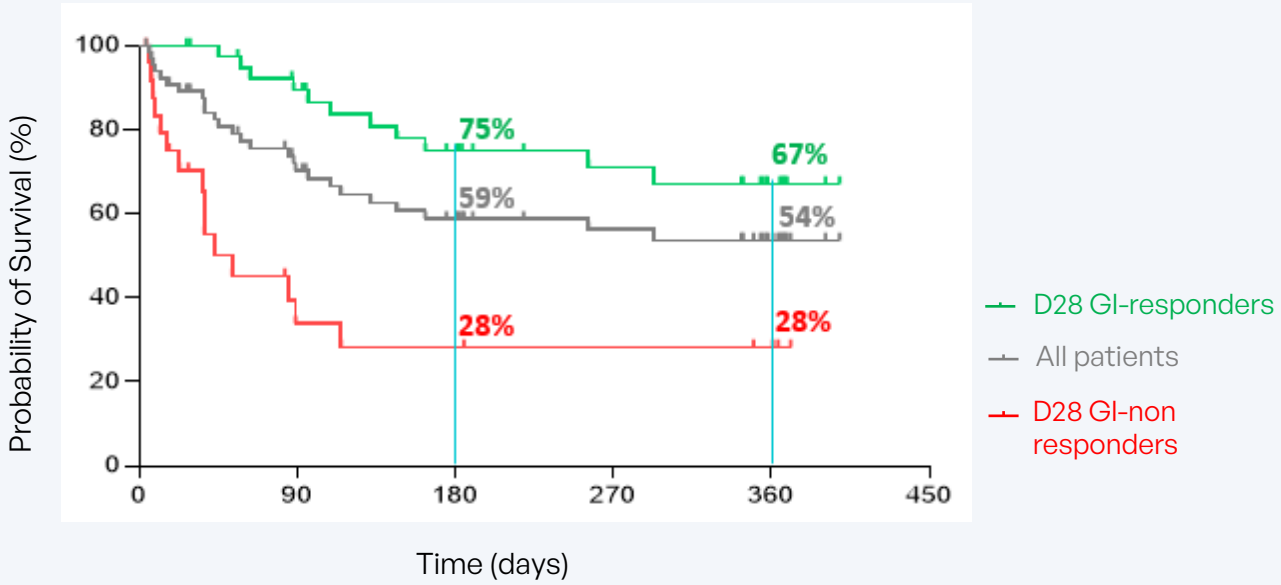
The study met its primary endpoint with a significant gastrointestinal overall response rate ($p < 0.0001$)

# 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



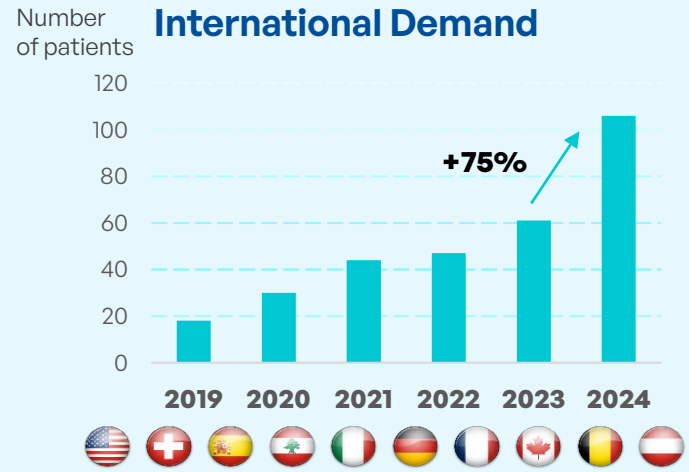

Xervyteg® demonstrates response-driven prolonged survival, far exceeding expected outcomes in third-line aGvHD, with **54% probability of survival at 1 year compared to 15% survival in historical control**

# 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

- Xervyteg® 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%)**

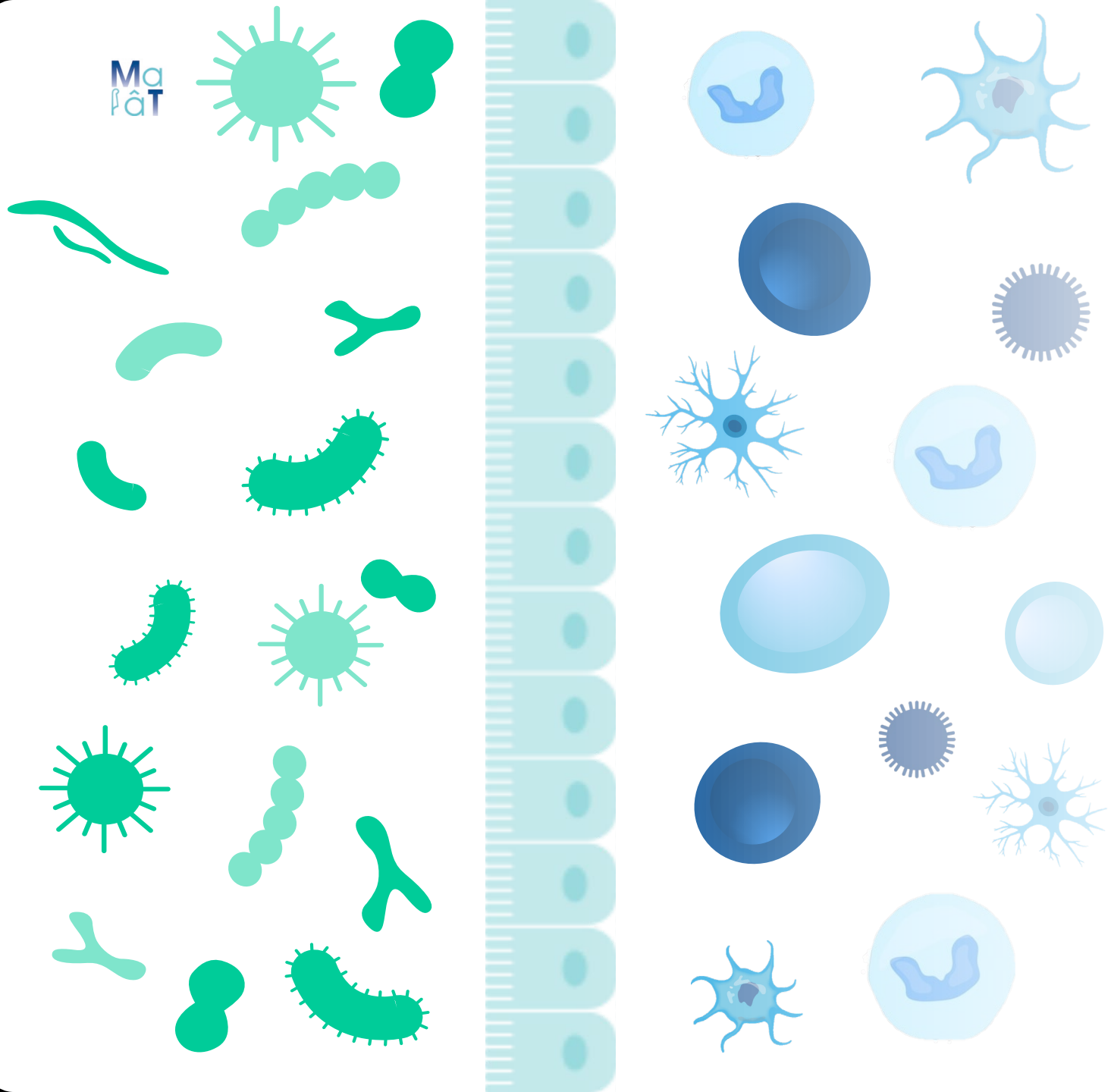
# Regulatory Path for Xervyteg® in Third-Line Refractory aGvHD: Established in Europe, Leveraging EU Results for Ongoing US Discussions

## In Europe

- **EMA Marketing Authorization Application filed** for Xervyteg® (MaaT013) **on June 2nd, 2025**
- Eligibility of Xervyteg® for the **centralized procedure confirmed by EMA** (Medicinal product status) and rapporteurs and co-rapporteurs appointed
- **Submission based on validated primary endpoint** (28 days GI-ORR) complemented with data on 1y-OS
- **Target H2 2026 for European marketing potential authorization**, commence **commercialization end of 2026**

## In the U.S.

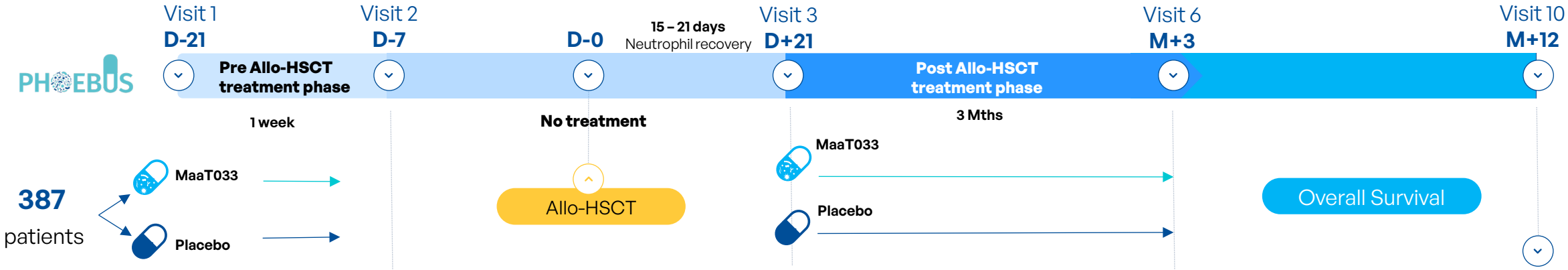
- **Open IND:** Ongoing dialogue with the FDA to expedite Xervyteg® clinical development plan including :
  - **Dedicated and optimized study for the US** leveraging ARES Phase 3 results. Targeting potential launch of U.S. Phase 3 study in 2025.
  - Plan to engage with the FDA to discuss a potential 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 Xervyteg®



# 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**

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

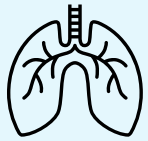
**Based on expected duration of recruitment, OS primary endpoint expected in 2027**

**~ 11k patients per year**

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

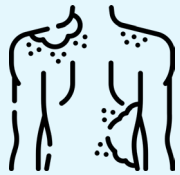
***Immune Checkpoint Inhibitors (ICI) significantly improve outcomes in solid tumor patients***

## 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-naive metastatic melanoma patients**

✓ **15/20**

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

✓ **.../35**

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

# Xervyteg® Evaluated in Phase 2 Randomized, Multicenter Clinical Trial in Melanoma

***Phase 2a PICASSO trial, fully recruited***

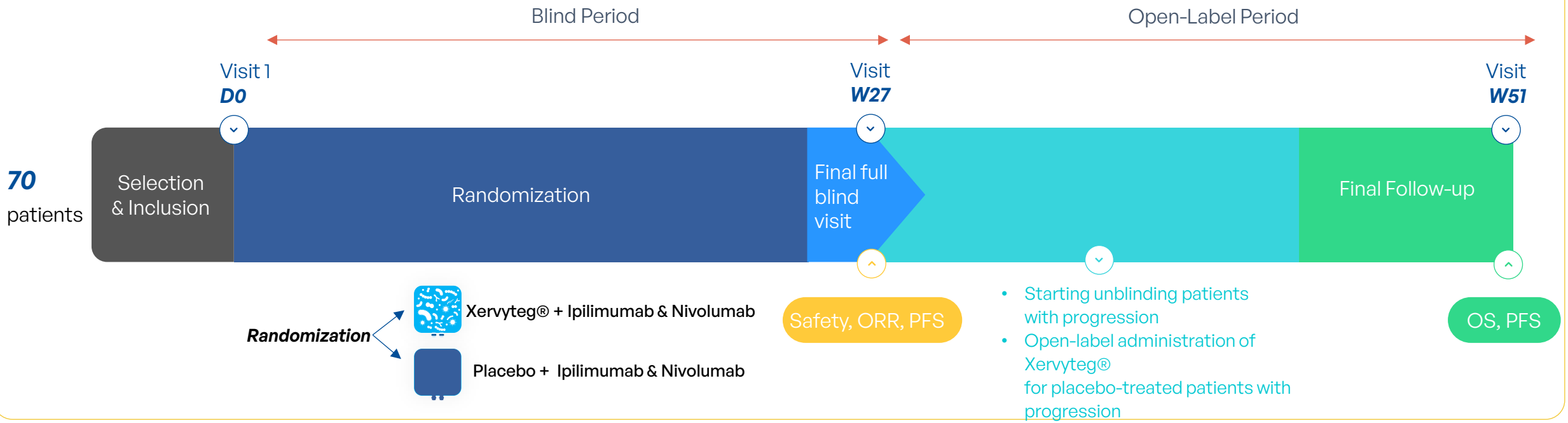
***Investigator Sponsored Trial*** (Assistance Publique - Hôpitaux de Paris) in collaboration with Institut Gustave Roussy

→ **Data expected in H2.25**

***Key study endpoints after 23 weeks of treatment:***

Xervyteg® safety profile and best-overall response rate vs placebo as add-on treatment to Ipilimumab + Nivolumab

***PICASSO RCT design***



# MaaT033: Favorable safety and tolerability profile in ALS
# Seeking Partners for Next-Phase Clinical Development

## Amyotrophic Lateral Sclerosis (ALS)

→ Could affect up to 60,000 patients in US & EU by 2040[1]

→ Paralysis and death 3 to 5 years after diagnostic [2]

→ Currently no curative treatment and few symptomatic treatments

## Rationale for Exploratory Utilization of MaaT033 in ALS

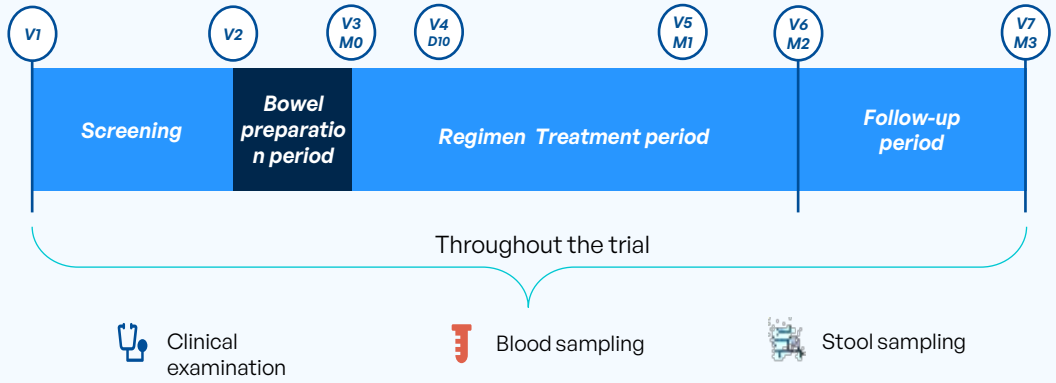
→ Microbiota-Gut-Brain axis is a multifactorial MoA which has high potential in neurodegenerative diseases, including ALS

→ 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

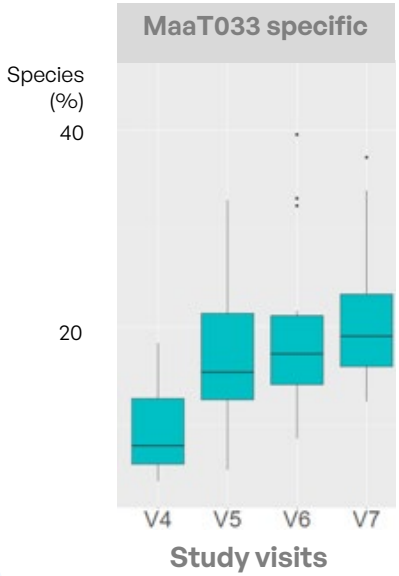
→ ***Pilot, open-label, Phase 1b*** study ***in France, N=15*** (NCT05889572)




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

→ ***Primary endpoint met, key highlights from full data review:***

- A favorable safety and tolerability profile, supported by biomarker and microbiome analyses
- Rapid, sustained engraftment of MaaT033 species within 1 month, maintained through follow-up
- DSMB & Scientific Committee support proceeding to Phase 2
- ALSFRS-R slope slowed from –0.7 to –0.3 pts/month (baseline to D84), suggesting slower progression, though interpretation is limited by short follow-up, limited sample size and single-arm Phase 1b design
- No variation at D84 in the levels of neurofilaments, a marker associated with neuronal injury in ALS




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

Study developed with: FILSLAN, act4 ALS-MND

In collaboration with:

[1] 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 | [2] 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


***HIT Products***
Donor-independent ecosystem candidate

***LEAD Products (MaaT03X)***

→ Activity in *in vitro* models (local and distal models)

***Candidate Products (MaaT034)***

→ Activity in 2 different mouse models

→ Product characterization

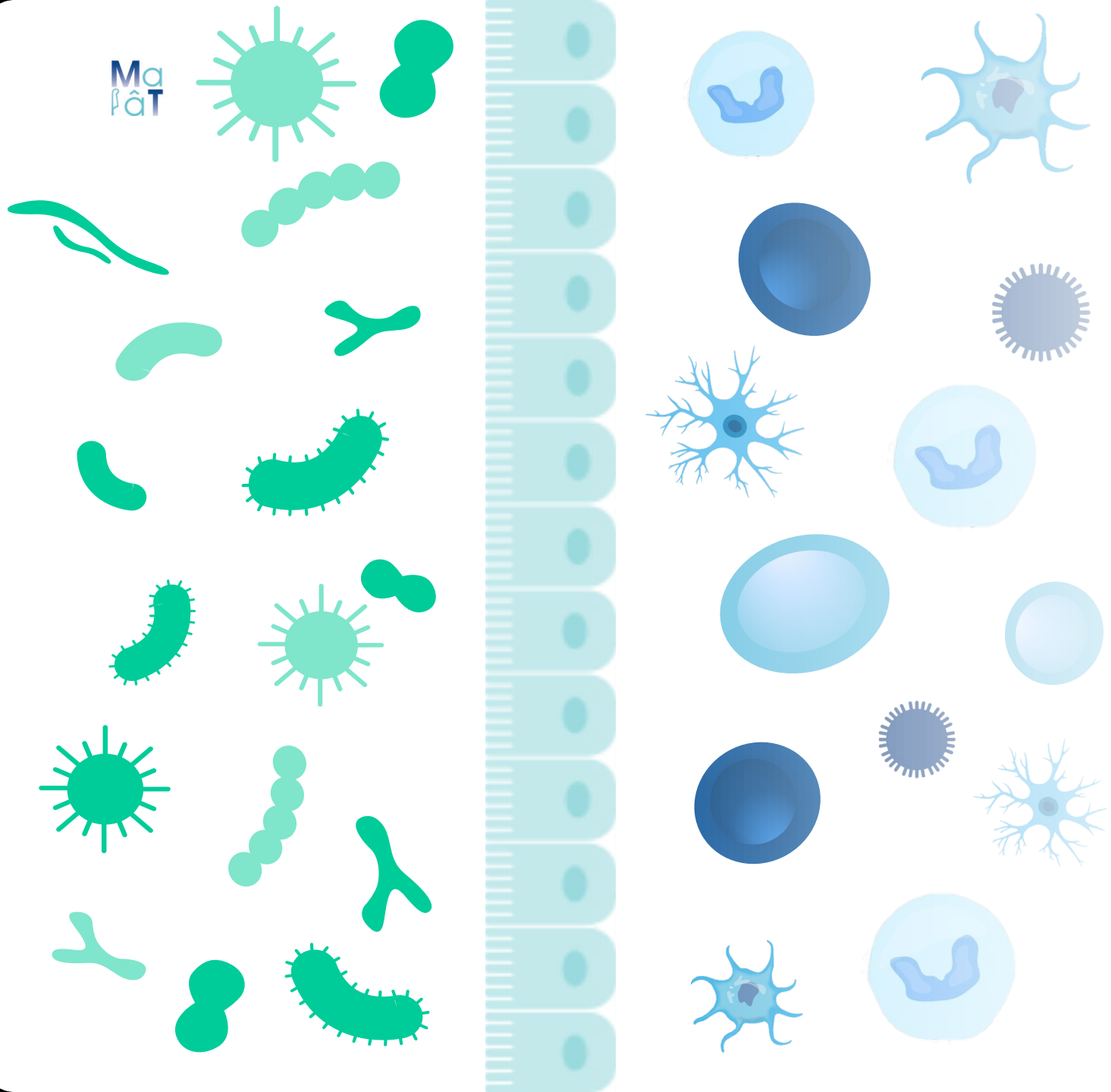
→ Safety and Dose assessment

***Upcoming Milestones for MaaT034***

→ Manufacturing of Clinical batches expected in H2.2025

→ FIH expected in 2026

Indication-specific drug candidates



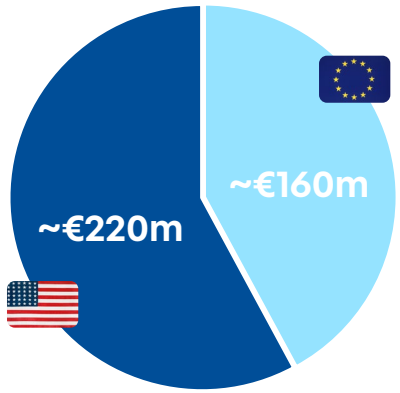
# Hemato-oncology Franchise Driving Value

# Xervyteg®: High-Margin Potential and Addressable Market Opportunity

## Addressable market in 3L*

~3,000 patients

3L GI-SR-RR/I-aGvHD

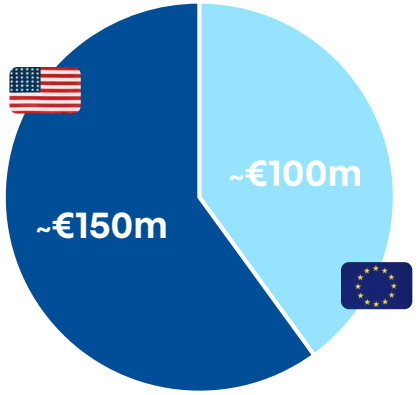



~€380m+

## Estimated Annual Revenues

65% Market penetration

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




~€250m+

- 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
EU + UK ; US + CA

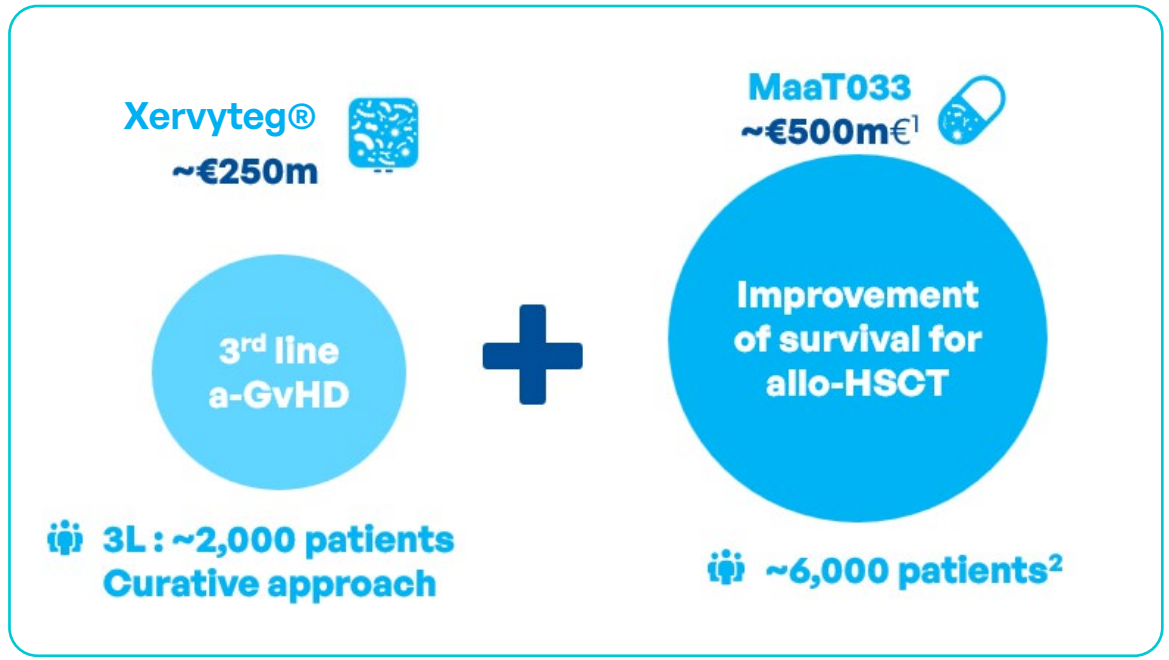
# Realizing Value through Partnership: Aligning Innovation with Unmet Medical Needs in Hematology

## 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 Xervyteg®
- **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

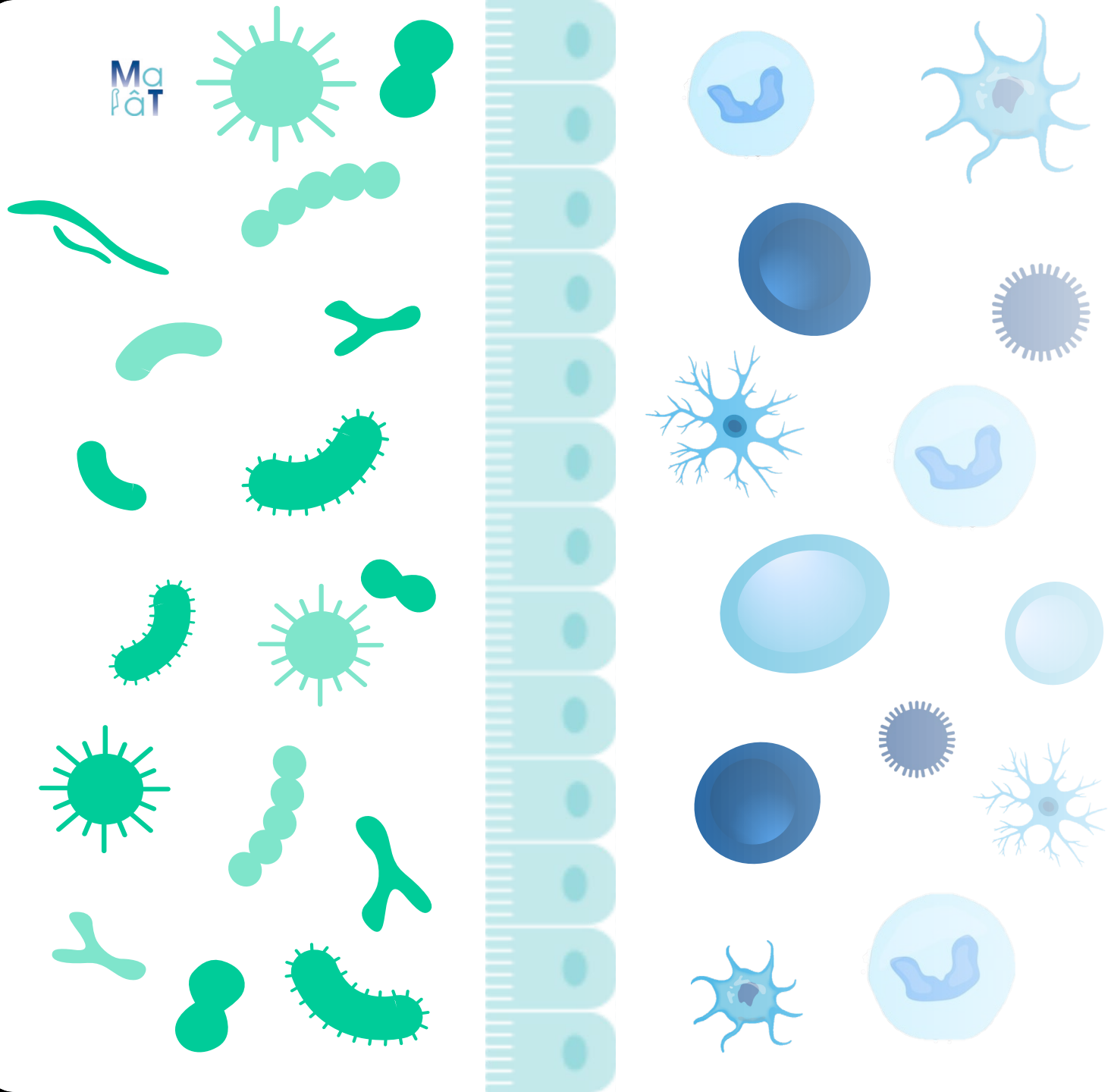
Significant potential to leverage partner's expertise in hematology, rare diseases, or hospital commercial operations.

## A very meaningful market opportunity




A Total market of
**~€750 m+**

[1]PYS EU5, US; [2] Per year



# End-to-End In-house cGMP Manufacturing Capabilities

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

**A dedicated 1,600m² 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**

| | |
|---|---|
| Xervyteg® | 9,000 bags/ year |
| MaaT033 | 1,300,000 capsules / year |
| MaaT03X | Up to 300,000 capsules / year |

**01**

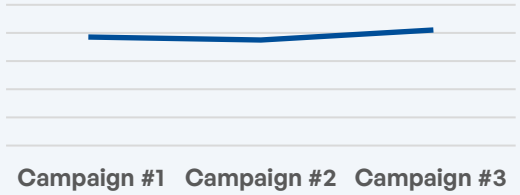
***Leading microbiome therapies fully integrated manufacturing and development platform:*** streamlined product development, scaleup and GMP process.

**02**

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

**03**

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




*Manufacturing yield based on FDA/EMA authorized processes*

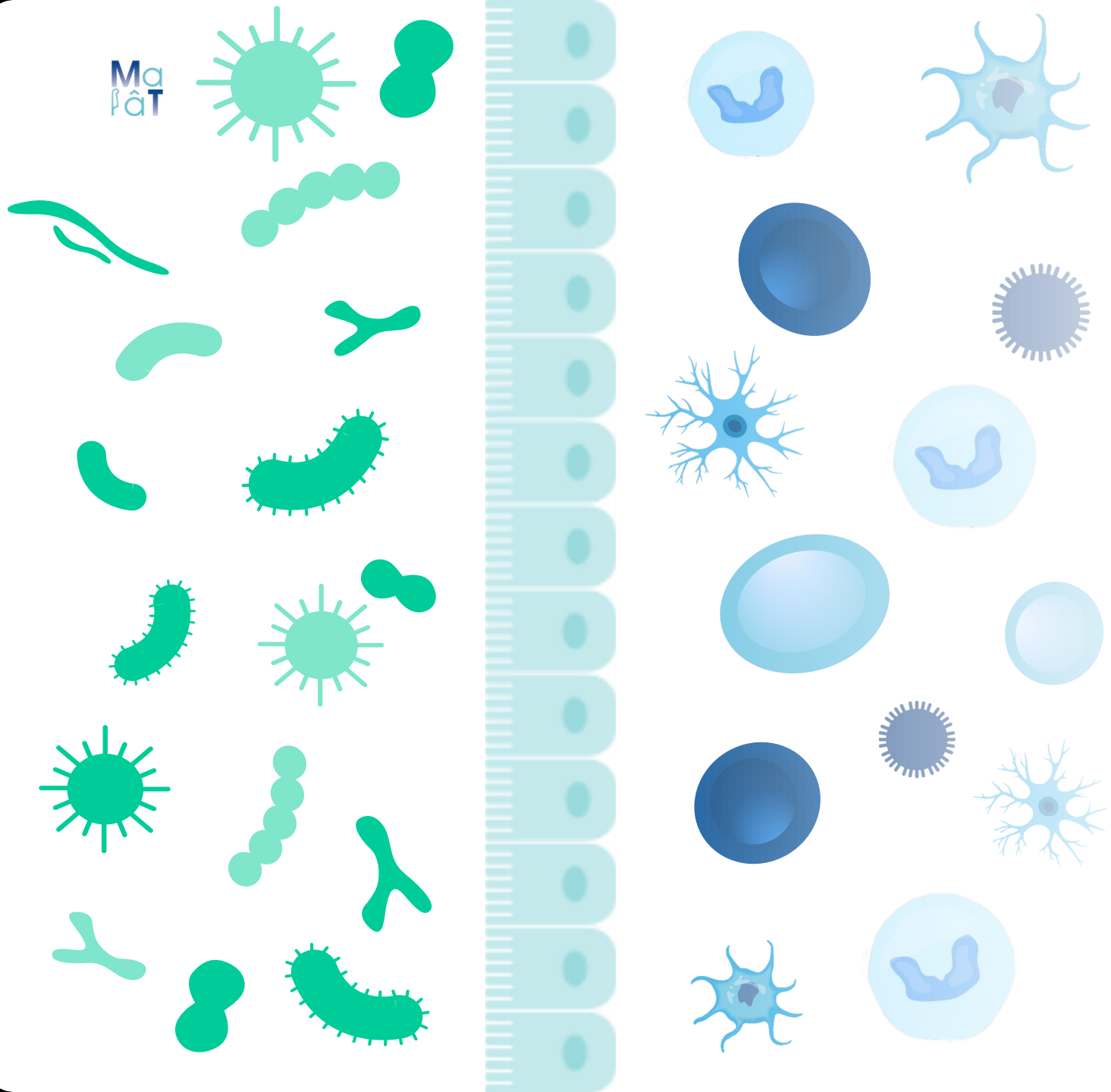
**04**

Currently used at 10% capacity

***Scalable up to commercial capacity***

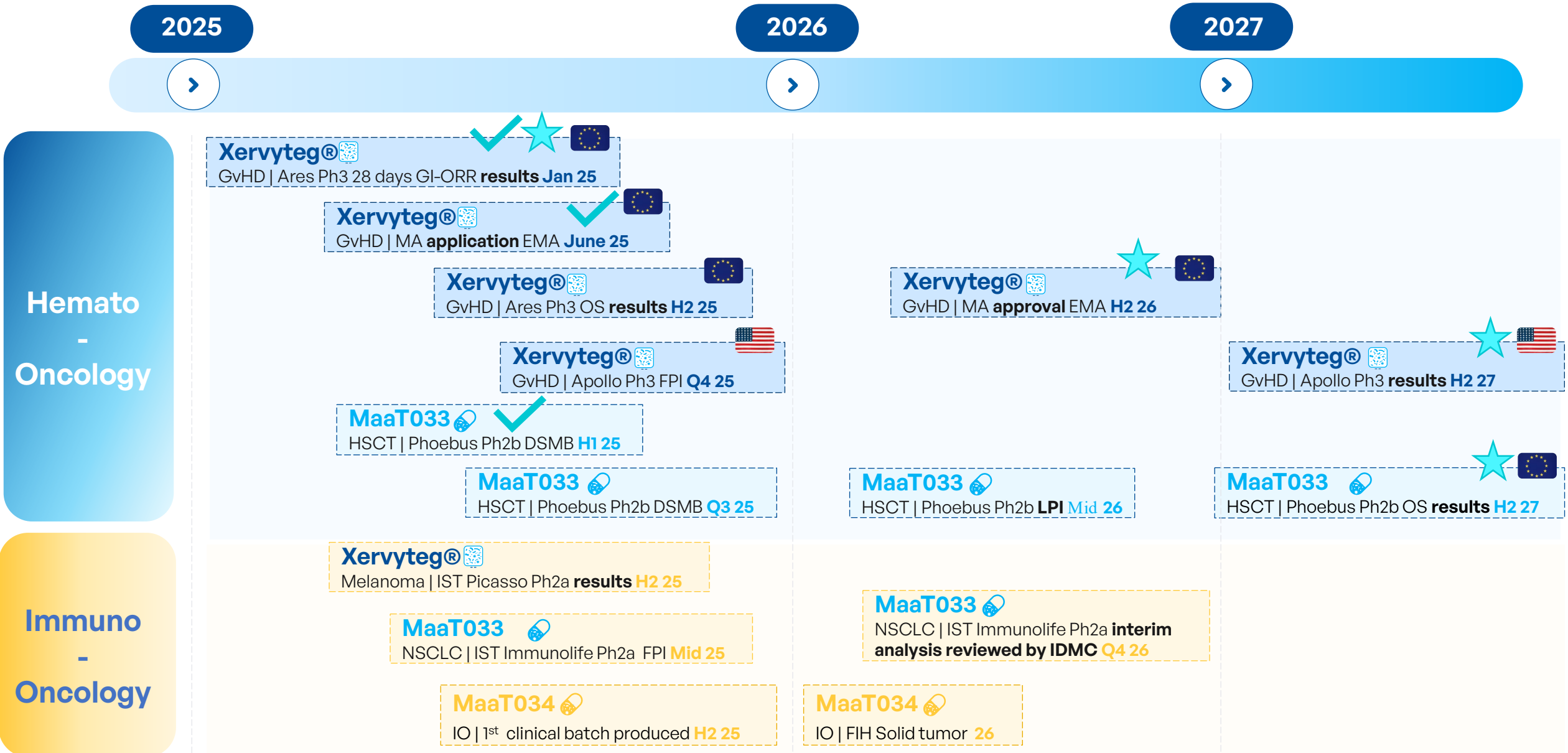

*Partnership with* Skyepharma

MANUFACTURED TO cGMP STANDARDS

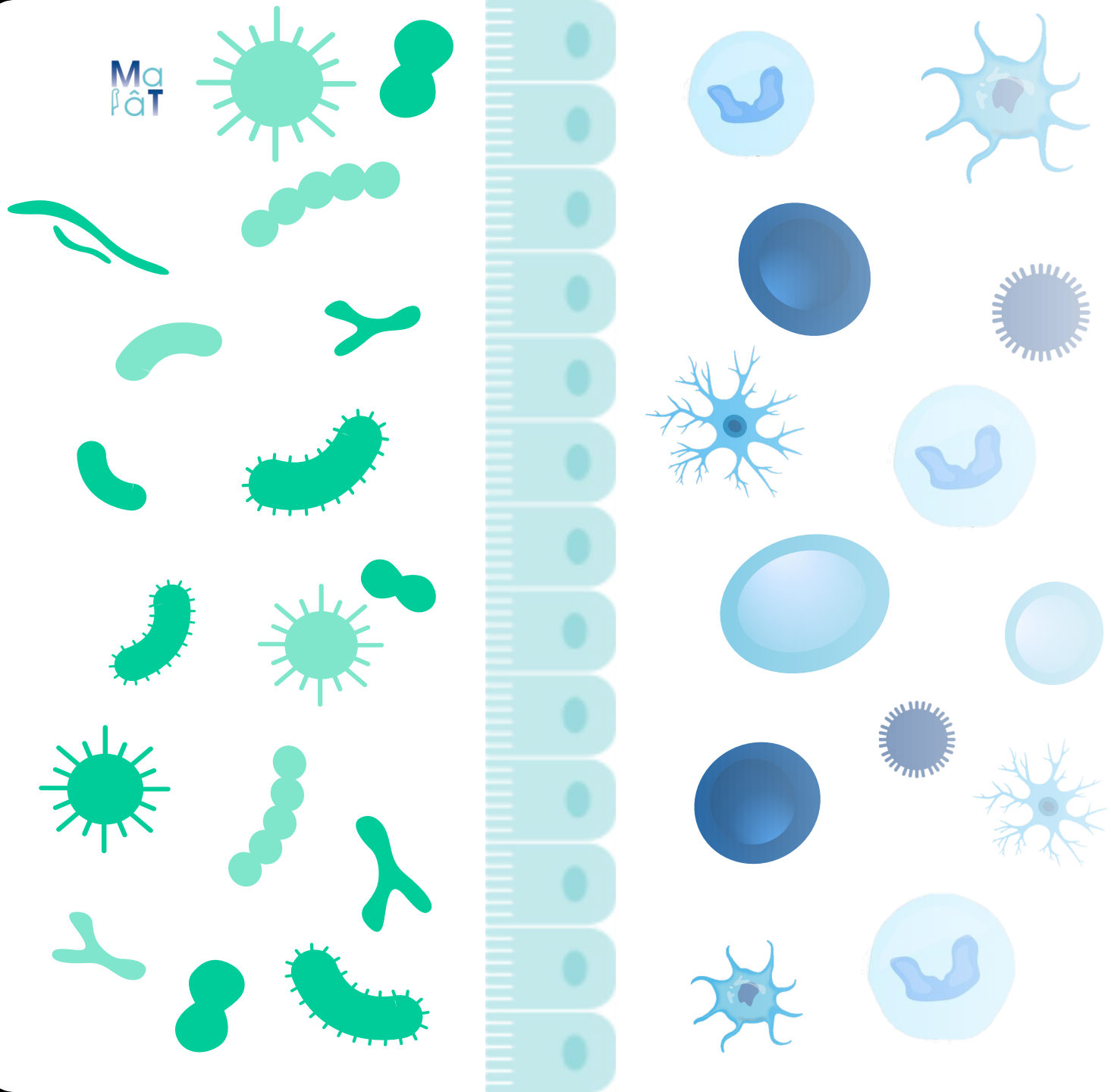


# Newsflow & Funding Opportunities

# Several Major Near-Term Value Inflection Expected Milestones




Legend: ★Key milestone ; ✓Achieved US market ; EU market ; Xervyteg® (pooled enema) ; Maat033 (pooled capsule) ; Maat034 (co-cultivated capsule)



# Thank you

MAAT LISTED EURONEXT

ELIGIBLE PEA PME