MaaT Pharma

Key Leader Opinion Discussion around ASH 2023

December 23

ASH 2023

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Our speakers today

Herve Affagard
MaaT Pharma
CEO & Co-founder

Mohamad Mohty, MD, PhD
Professor of Hematology
Head of Hematology and Cellular Therapy Dpt.
Saint-Antoine Hospital
Paris, France

Florent Malard, MD, PhD
Professor of Hematology
Sorbonne University, INSERM
Hematology and Cellular Therapy Dpt.
Saint-Antoine Hospital
Paris, France

MaaT Pharma

Introduction & Strategy

December 23

Herve Affagard
MaaT Pharma
CEO & Co-founder

MaaT Pharma: A late-stage clinical biotech, leading the way in Microbiome therapies in oncology

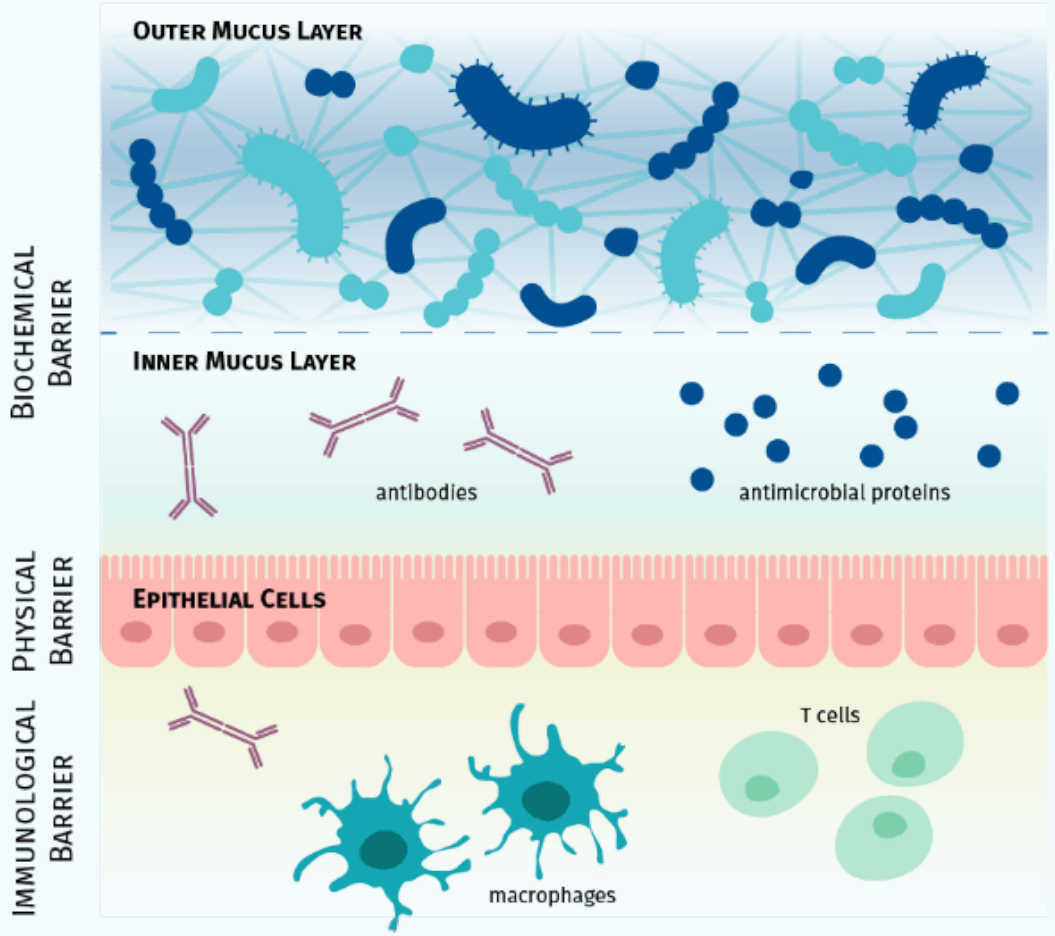
LEADER	Listed on **Euronext (MAAT.PA)** global leader in the development of **Microbiome Ecosystem Therapies in oncology to enhance patient survival**
EXCELLENCE	Founded in **2014** | First Patient Treated in **2016** | **Pooling Pioneers** | First **FDA-Approved** Pooled Microbiota Trial | **7 Years Seed to Phase 3** | Factory Built in **Record 12 Months**
AI ENGINE	**Proprietary gutPrint® metagenomics research engine** driving product candidate generation by leveraging the data generated from MET-N products, to develop full synthetic microbiome MET-C programs using AI tools
MET-N	**Lead asset MaaT013 in Phase 3, available through Early Access Program** in aGvHD with results in 2024 and expected commercial launch in 2026 | **Second generation asset MaaT033** pooled capsule currently in **Phase 2b**
MET-C	**Ground-breaking co-culture donor independent MET-C platform** with first asset **MaaT034**, a full synthetic microbiome capsule **progressing towards IND in IO**
cGMP	**Largest European cGMP production facilities for microbiome** supporting our development endeavor
FINANCE	**Revenue** from **EAP of MaaT013 in aGVHD of 1.8m€ for the first three quarters of 2023** **Cash position of 31,7m€** with a **horizon** into **second quarter of 2024**

Host – Microbiota Interactions are Critical for a Functional Immune System

A rich and diversified gut ecosystem actively modulates the immune system functionality

01 **A diversified microbiome** contributes to the **education and modulation of our immune system** throughout life

02 Bacterial **richness** and mucus layer prevent colonization by pathogens and improve gut barrier



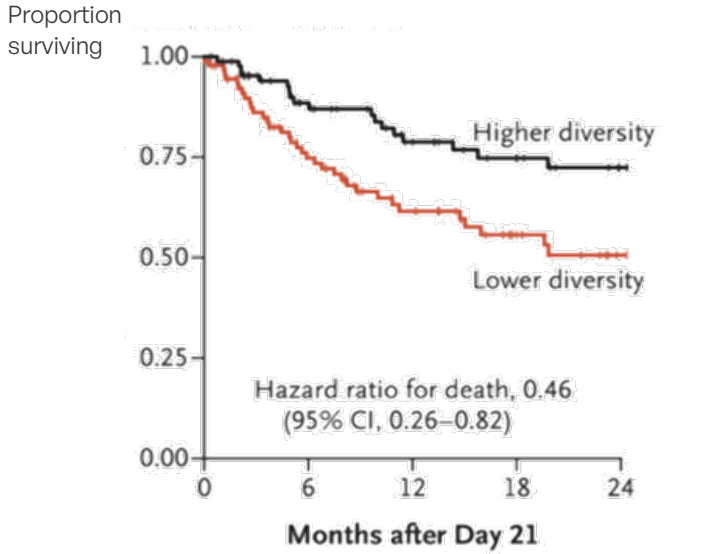
Cross-section of a healthy gut

80% Cellular host defense localized in the gut

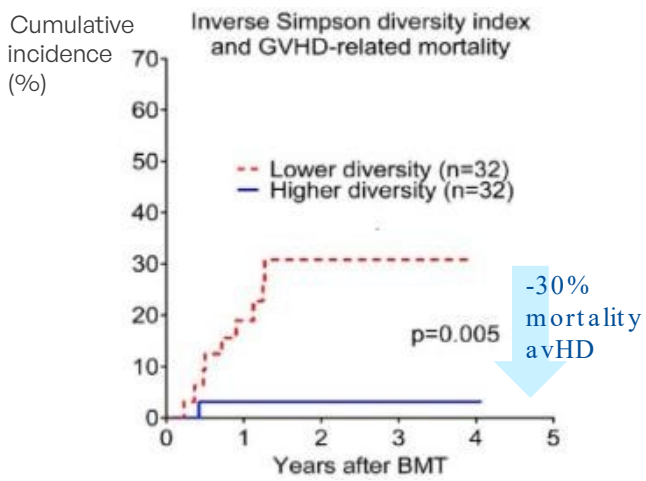
Higher gut microbiome diversity is associated with better outcome in oncology

Liquid Tumors

Higher survival rate in patients receiving allo-HSCT *[1]



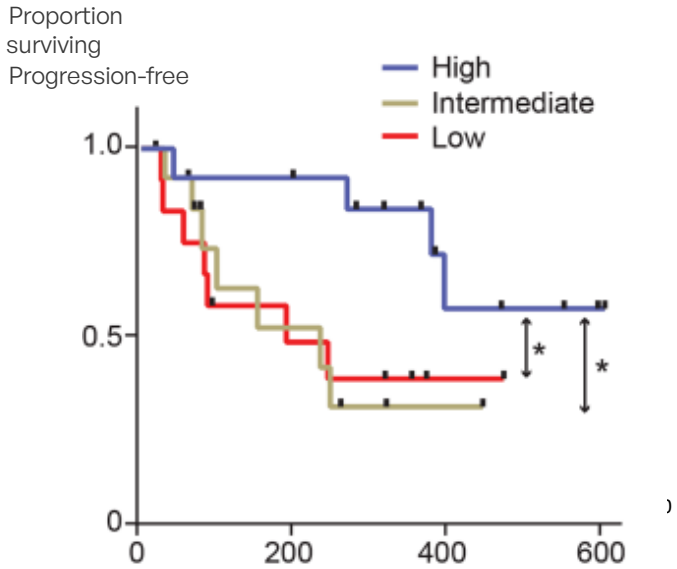
Lower incidence and lower mortality from aGvHD *[2]



MaaT Pharma MET
Inverse Simpson (mean): **24**

Solid Tumors

Higher response rate to ICI* in patients with metastatic melanoma [3]



* allo-HSCT: allogeneic hematopoietic stem cell transplantation; aGvHD: acute Graft-vs-host-Disease; ICI: Immune Checkpoint Inhibitors

[1] Peled, J.U. & al N Engl J Med 2020;382:822-34; [2] Ghani, 2021 ; Jenq RR. et al, Biol Blood Marrow Transplant 21 (2015) 1373e1383; Pamer, Blood, 2014 ; [3] Gopalakrishnan et al., Science, 2017, see also Routy et al, Science, 2018 ; Vetizou et al Science 2015;

A Step-by-Step Increasing Value Creation Strategy Backed by Leading Capabilities in Microbiome Drug Candidate Production

gut Print

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

MaaT013

MaaT033

POOLING

MaaT013 MaaT033

Pooled microbiota → Maximized richness → Standardized (450 OTU ± 3%)

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

MaaT034

MaaT03X

Original microbial ecosystem

Master bank

Working Bank

Unlimited Co-Culture Scaling

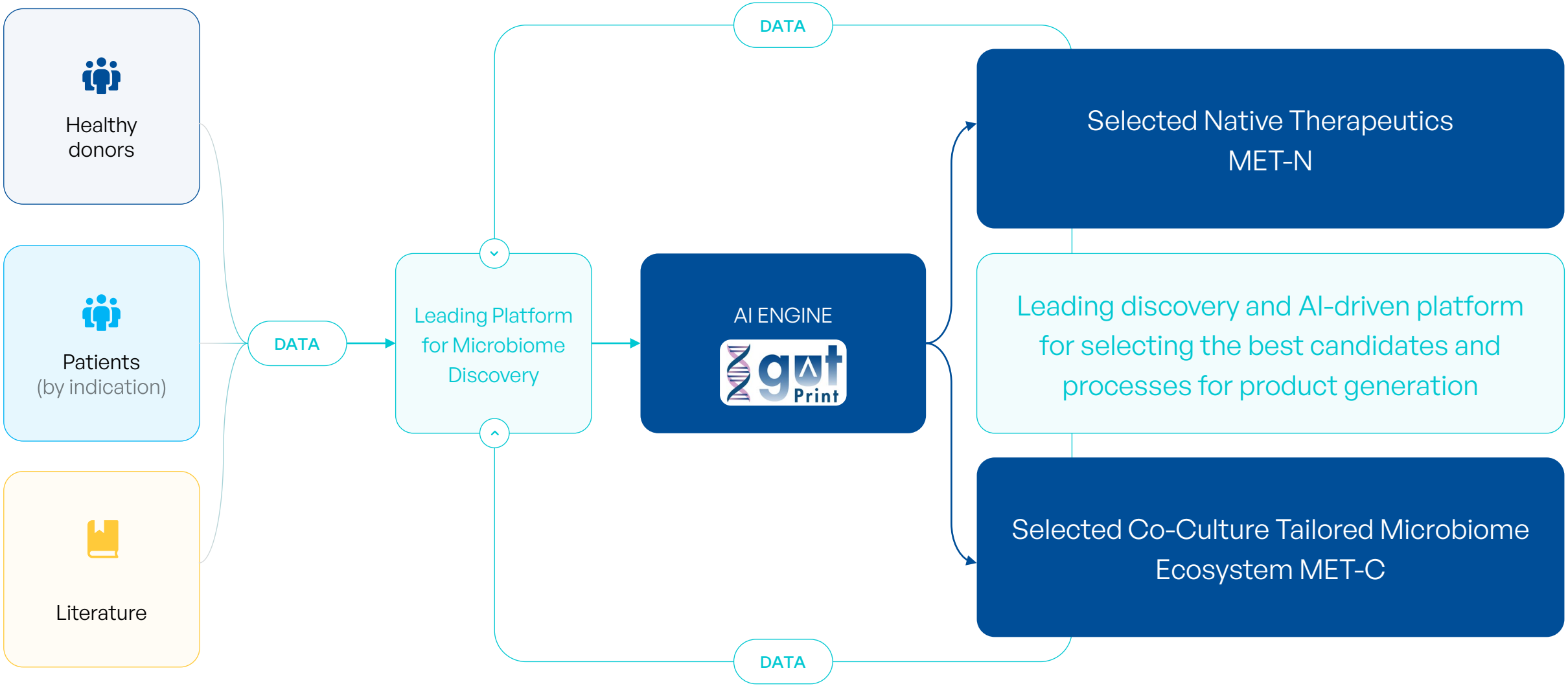
Multistep co-culture cGMP proprietary process

MET-C product

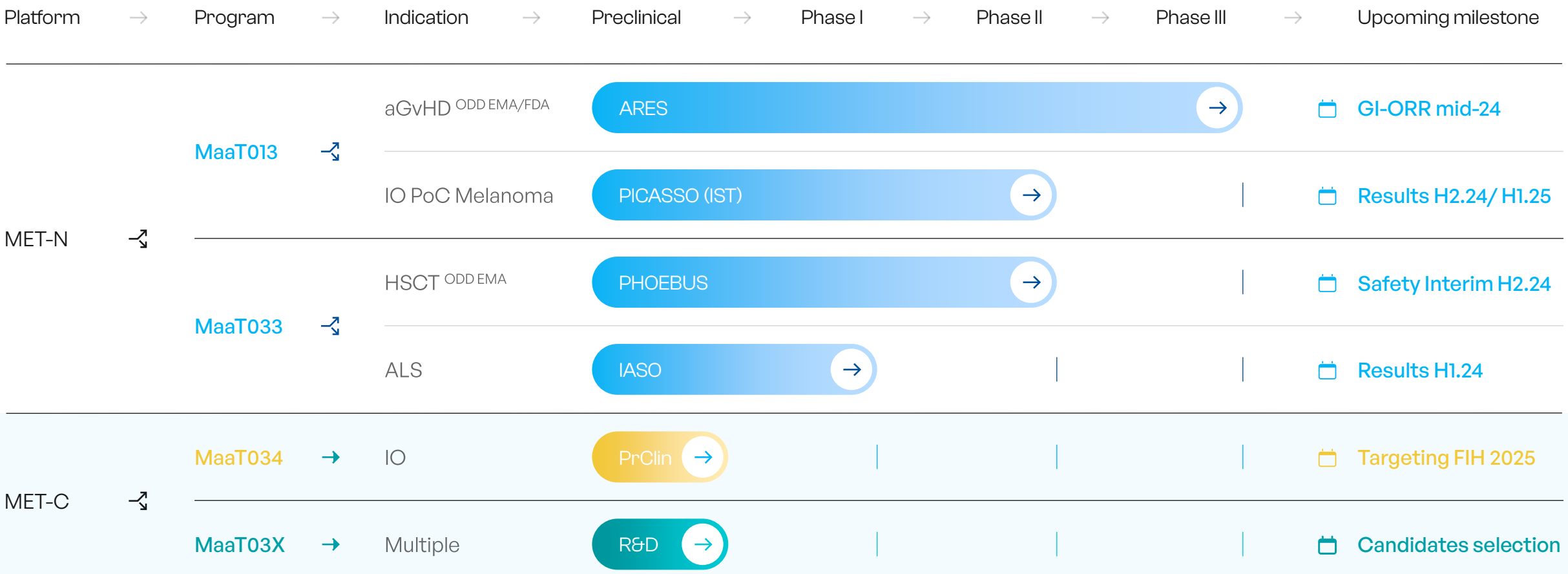
Leading capabilities in microbiome drug production

~10 000 treatable patients per year

Cutting-edge Research Engine Powered by Metagenomics and AI-driven Candidate Selections

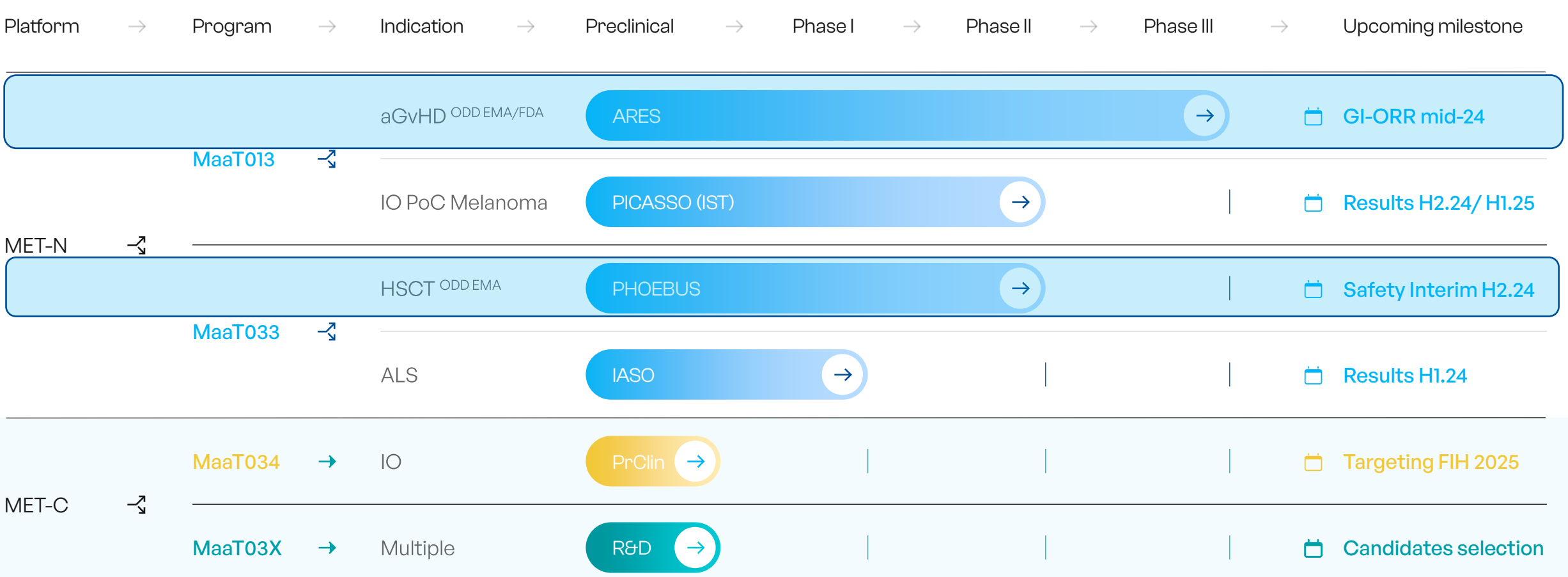


A robust pipeline of late and early assets



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

A robust pipeline of late and early assets



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

Results from Early Access Program in Europe MaaT013 for Refractory GI-aGvHD

Mohamad Mohty, MD, PhD
Professor of Hematology
Head of Hematology and Cellular Therapy Dpt.
Saint-Antoine Hospital
Paris, France

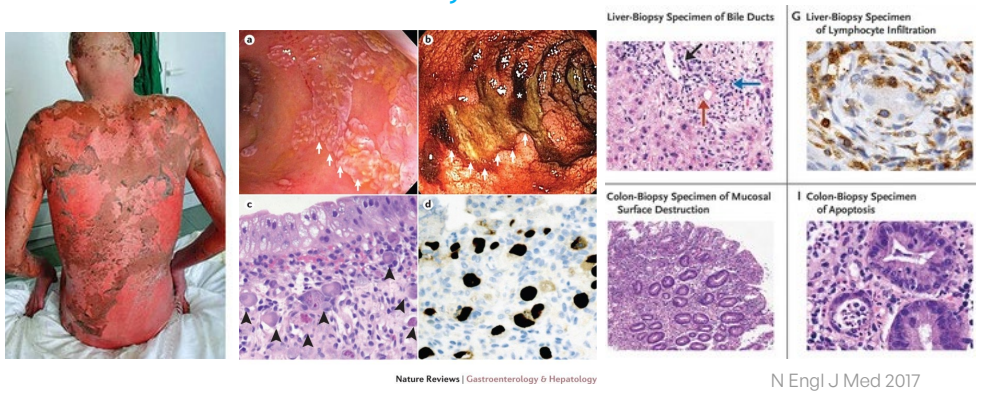
Microbiome Restoration with MaaT013: A Maximum-Density Product for Fast Engraftment in Acute Situations

- **Curative approach**

Characteristics	**Pooled microbiota**: high-richness, high-diversity, full ecosystem, **Microbiome Ecosystem Therapy containing Butycore®**
Administration	**3 doses** (enema bag)
Current indication	**Gastrointestinal acute Graft-versus-Host Disease** (GI-aGvHD)
Available Clinical Data	**HERACLES Phase 2** Clinical Trial, N=24, 2L **Early Access Program (EAP),** data from N=111, 3L-6L, program still ongoing **> 200** patients treated to date

MaaT013 Aims to Enhance Survival in Patients with Steroid & Ruxolitinib Resistant/Refractory aGvHD through Gut Microbiota Restoration

3 main tissues affected: Skin, Gut and Liver



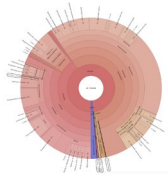
N Engl J Med 2017

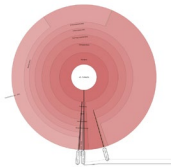
Chemotherapy Antibiotics

→ Irradiation

→ Immunosuppressors

Patients with liver tumors


Before

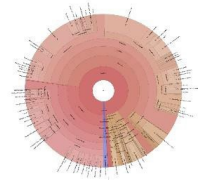

After

Allogenic Hematopoietic Stem Cell Transplantation (allo-HSCT)

~ 22 000

patients/yr [2]

Maat013 Treatment



Loss of diversity (dysbiosis) → **aGvHD**

→ Infections

→ Complications

~ 10 000 patients/yr [3]

~ 30% steroid & ruxolitinib-resistant [4]

→ **~ 3 000** patients/yr, no SoC

→ **~ 80%** 2-month mortality [4]

[1] Peled et al, NEJM 2020 ; [2]EU5 + US : (~ 20 500 primary procedures with an additional 7%-10% recurring), [3]EU5 + US, [4]REACH1 study ; SoC: Standard of Care

Early Access Program (n=111) Ongoing in Europe

Main inclusion criteria

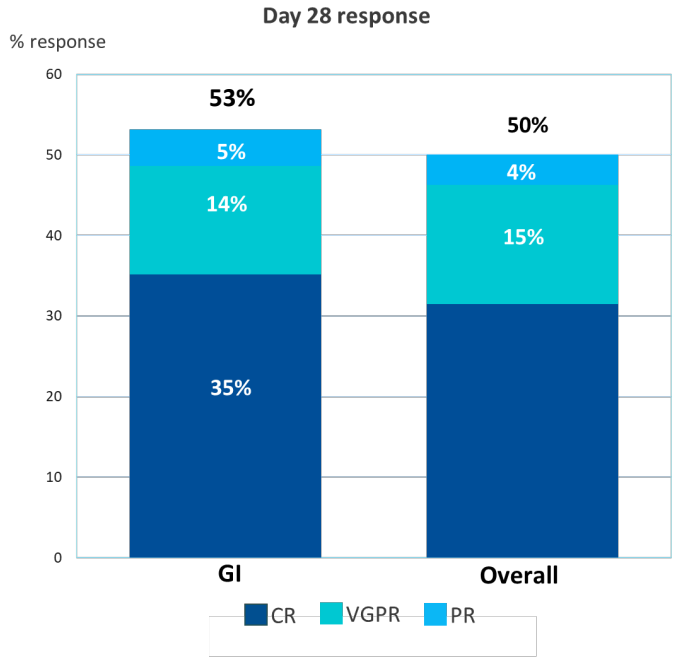
- Steroid refractory / dependent
- Acute GVHD with gut involvement, grade II to IV
- Any line of treatment
- MaaT013 used as a monotherapy and/or combination therapy
- ≥ 12 hours discontinuation of systemic antibiotics surrounding MaaT013 administration
- Patient not eligible to ongoing clinical trial (ARES - NCT04769895)

Patients Characteristics

Gender, n (%)	Male	60 (54%)
	Female	51 (46%)
Age at first MaaT013 administration (years)	Median [range]	57 [15;74]
Number of previous lines of treatment, n	Median [range]	**3 [1;6]**
Steroid status	**Steroid refractory-aGvHD**	**94 (85%)**
	Steroid dependent-aGvHD	17 (15%)
Type of aGvHD	Classical	70 (63%)
	Late onset	12 (11%)
	Hyper-acute	13 (12%)
	Overlap syndrome	16 (14%)
GvHD grading (MAGIC), n (%)	I	0
	II	10 (9%)
	III	**54 (49%)**
	IV	**47 (42%)**

Global EAP Population (n=111, +30 vs 2022)

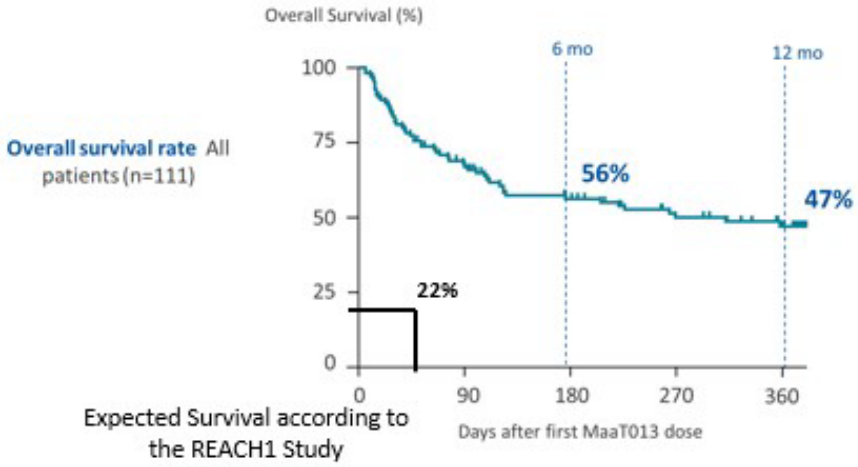
Response Rate

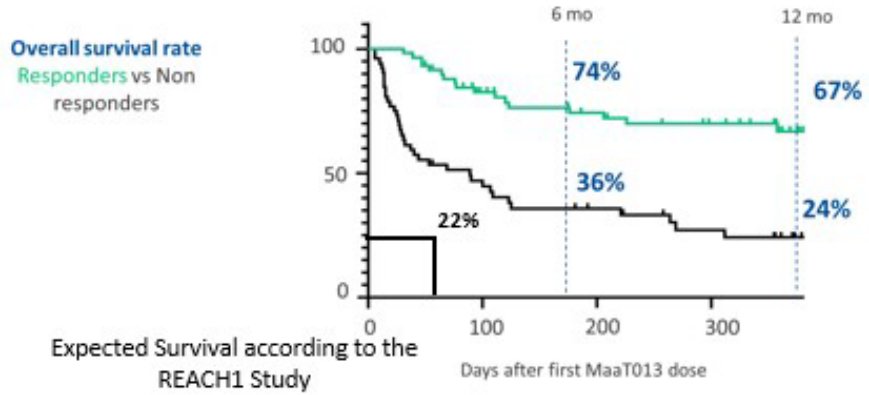


> n=111, GI-aGVHD : 49% grade III, 42% grade IV, up to 6 lines of prior treatments (median 3) 94/111 received ruxolitinib

> Good tolerability and safety profile

Overall Survival

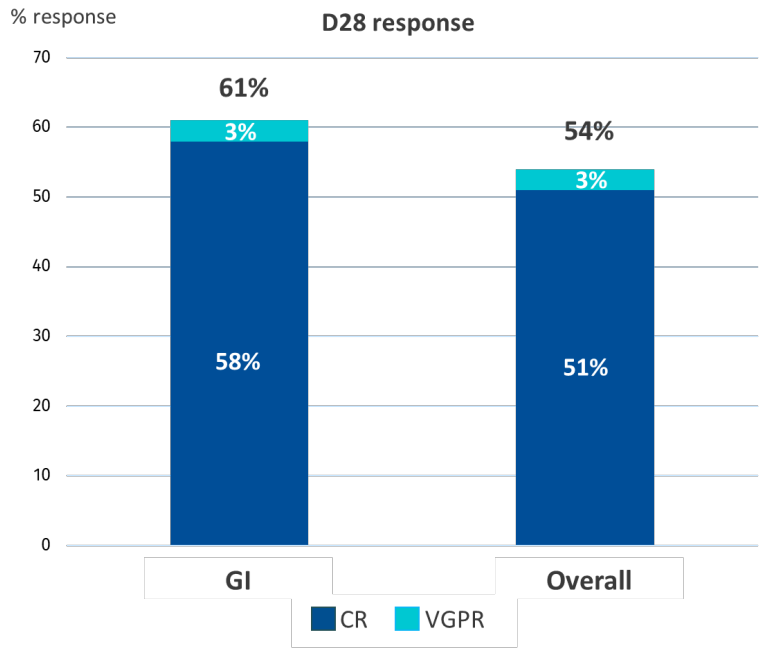




Clinical response to MaaT013 translates to an increased overall survival

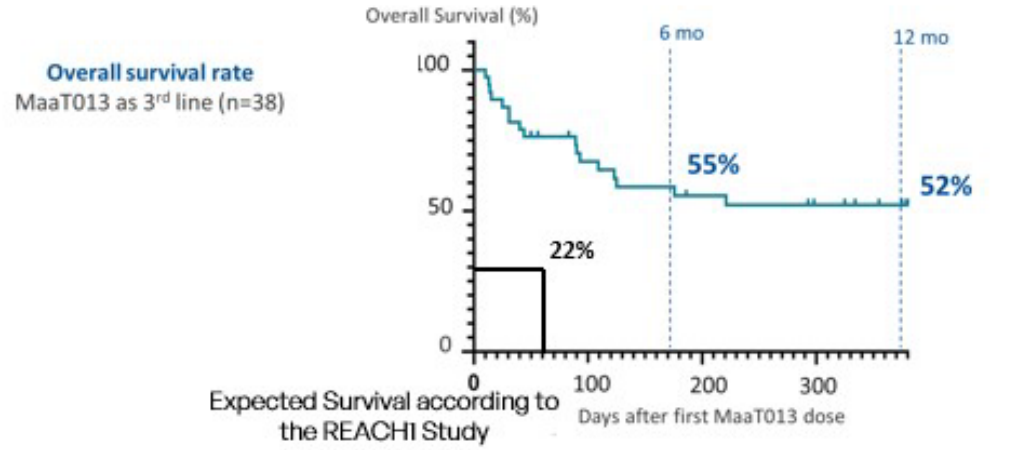
Focus on steroid 1L and ruxolitinib-refractory 2L patients (n=38): « ARES-like patients »

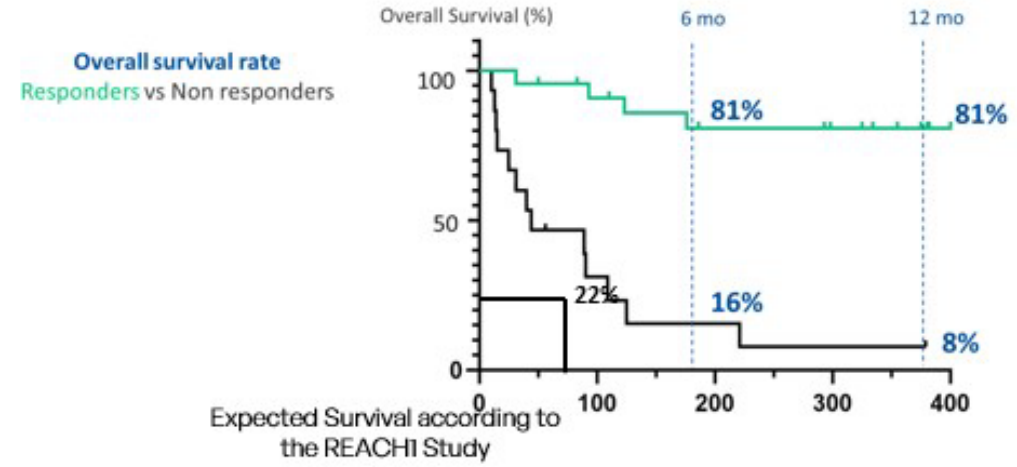
Response Rate



> n=38 – ARES like population ruxolitinib-refractory in 2nd line, MaaT013 given in 3rd line

Overall Survival





GI-response strongly correlates with survival, especially in this subgroup of patients

Good tolerability and safety profile in aGVHD population

- **16% of EAP patients** presented **adverse events possibly related** to MaaT013: GI symptoms in 3 patients, infectious complications in 15 patients
- **No pathogen transmission** reported.
- No death was attributed to MaaT013 administration with 55 patients alive at last follow-up.

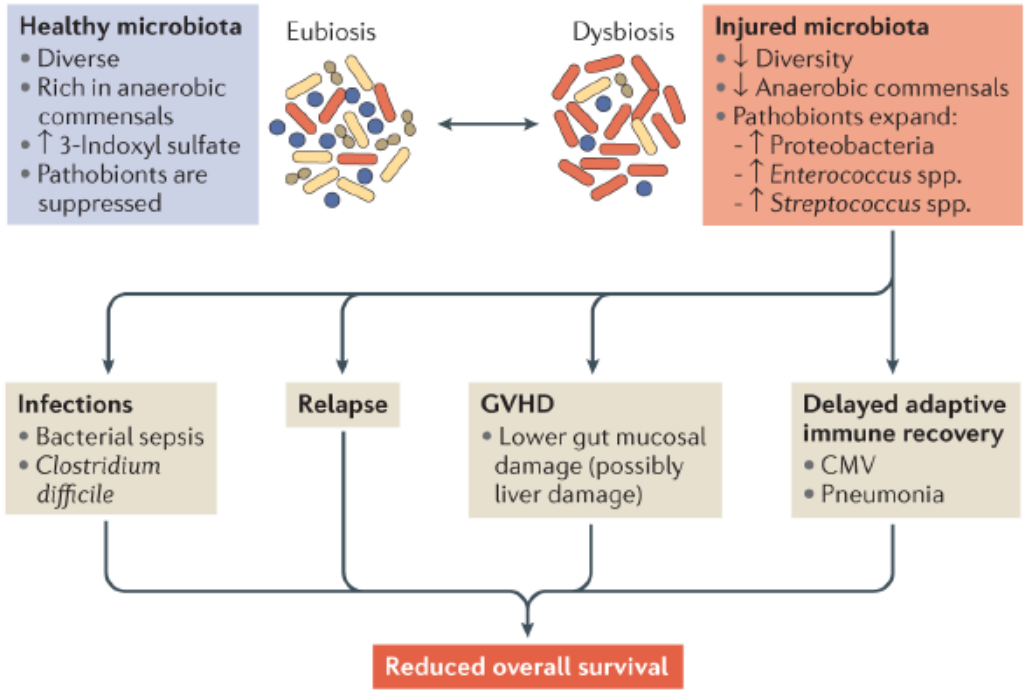
High response rate in refractory GI-aGVHD

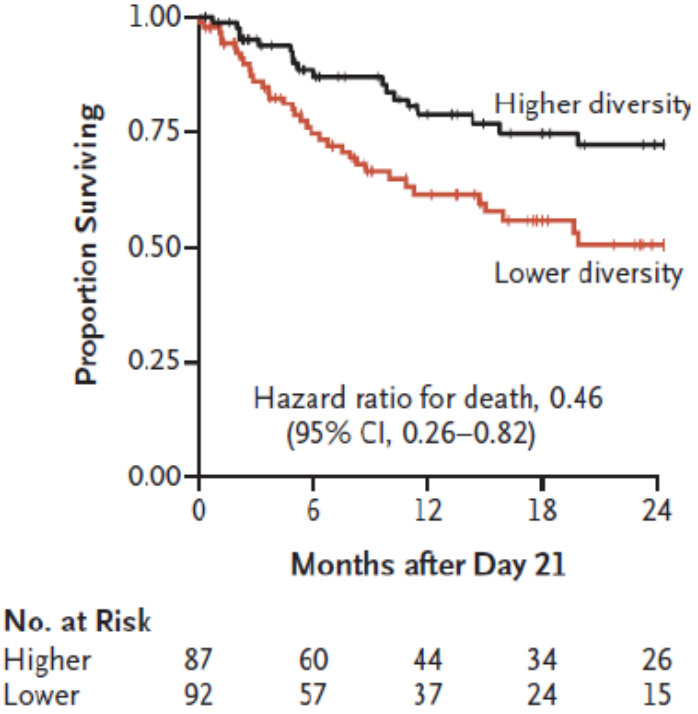
- **MaaT013 is safe** and translates into a **high response rate in refractory aGvHD patients**
- The benefit on GI-response positively and significantly **impacted OS in responder patients**
- Ongoing **Phase 3 clinical trial** in 75 patients with steroid- and ruxolitinib-refractory aGvHD patients (**NCT04769895**)

PHOEBUS trial: Multicenter randomized, double blinded phase 2b trial evaluating MaaT033 to improve outcomes in patients receiving allo-HSCT

Florent Malard, MD, PhD
Professor of Hematology
Sorbonne University, INSERM
Hematology and Cellular Therapy Dpt.
Saint-Antoine Hospital
Paris, France

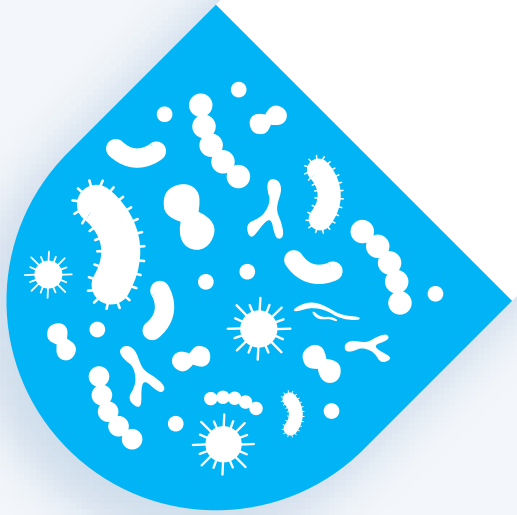
Scientific rationale for the development of MaaT033 in allo-HSCT





- Higher diversity of the gut microbiota before allo-HSCT and at neutrophil engraftment is associated with higher survival and lower risk of death post transplantation (Peled, 2020).
- Without intervention, the gut microbiota composition after intensive chemotherapy and antibiotics remains altered (Rashidi, 2022).

MaaT033 - The oral ecosystem microbiome capsule for adjunctive and maintenance therapy



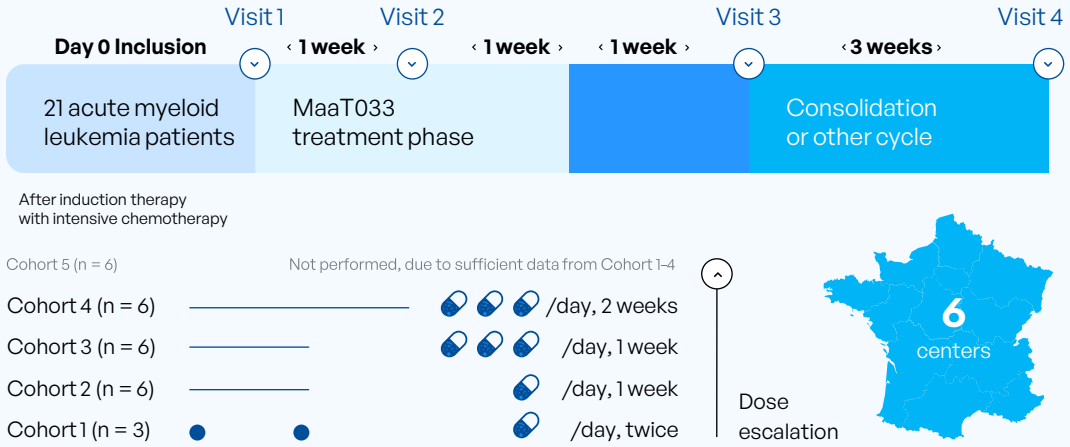
Adjunctive and Maintenance therapy, on top of standard of care, for allo-HSCT patients

Characteristics	**Pooled microbiota** : high-richness, high-diversity, full ecosystem, **Microbiome Ecosystem Therapy containing Butycore®**
Administration	**Oral** (a lyophilized capsule)
Treatment schedule	**Pre allo-HSCT** MaaT033 (3 capsules per day) for 1 week, between Day-21 (D-21) and D-7 before allo-HSCT (Day 0, D0). **Post allo-HSCT** MaaT033 (3 capsules per day) will be resume at neutrophil recovery (around D+18) and pursued up to 90 days after allo-HSCT.

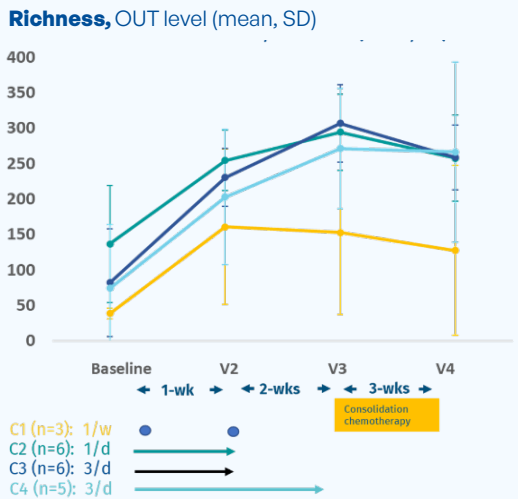
Study sponsored by MaaT Pharma

Phase 1b CIMON study: Positive dose ranging study with promising engraftment and safety data

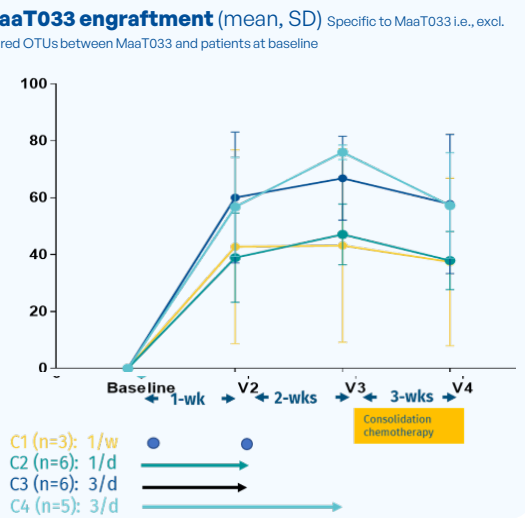
Phase 1b study aimed to determine MaaT033 dose for further clinical development



MaaT033 induces an increased microbiota richness at OTUs level



MaaT033 bacterial engraftment is inversely correlated with patients' baseline microbiota richness



First clinical POC of MaaT033 oral formulation

Robust and persistent engraftment

Engraftment following MaaT033 treatment correlated with increased anti-inflammatory markers.

Good safety profile:

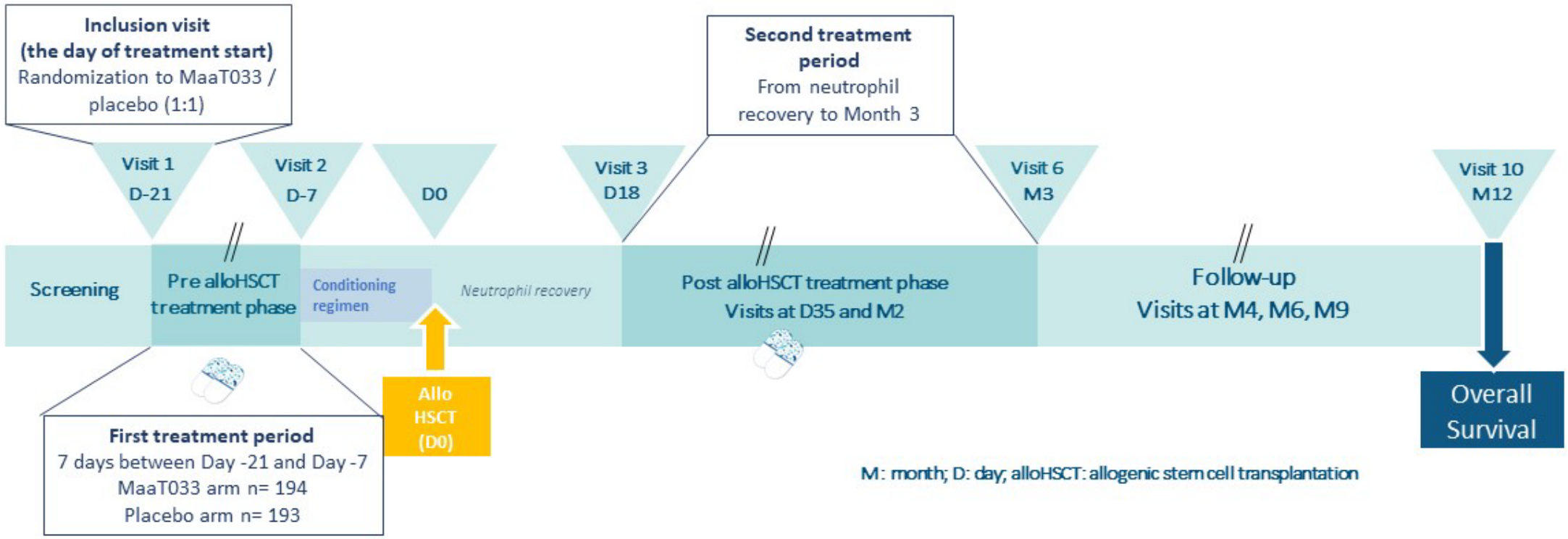
21 patients exposed, 20 completed | 100% drug compliance | 4/4 positive DSMB meetings

Main Objectives of the Phase 2b PHOEBUS

- Primary: Overall survival at 12 months after randomization
- Secondary: Evaluation of
  - Safety
  - GvHD-free survival at 12 months after allo-HSCT
  - Incidence of grade 2-4 and grade 3-4 aGvHD within 6 months after allo-HSCT
  - Cumulative incidence of cGvHD
  - Cumulative incidence of non-relapse mortality, of infectious-related mortality and GvHD-related mortality within the first 12 months after allo-HSCT
  - Relapse-free survival (RFS) and GvHD- Relapse-free survival (GRFS) at 12 months
  - Proportion of patients with severe infections within 12 months after allo-HSCT
  - Quality of life (QoL)
  - Microbiome composition and evolution

Study Flow Chart

→ 387 patients in a **randomized, double-blind, placebo-controlled, international** study



Stratification

•**Donor-host crossmatch**: HLA-identical (geno-identical and pheno-identical 10/10) versus HLA-mismatch (8/10, 9/10 and haplo-identical)

•**Disease risk index** (low-intermediate versus high-very high).

Main inclusion criteria

- Patients aged ≥ 50 years old
- Presence of a hematologic malignancy for which an allo-HSCT is indicated with a reduced toxicity or reduced intensity conditioning regimen
- Patients with polynuclear neutrophils >0,5 x G/L
- Patients having received wide spectrum antibiotics within the last 90 days prior to inclusion
- Use of wide spectrum antibiotics is defined as use of at least 3 days of antibiotics within the last 90 days prior start of allo-HSCT conditioning.
- Refer to the current study protocol re the list of wide spectrum antibiotics.
- Karnofsky index ≥ 70%
- Availability of a sibling donor, an unrelated stem-cell donor or a familial haploidentical donor
- Written informed consent

Main exclusion criteria

- Patients planned to receive a **non myeloablative conditioning regimen** (2 Gray Total Body Irradiation +/- purine analog, fludarabine & cyclophosphamide or equivalent)
- Patients planned to receive a **conventional myeloablative conditioning regimen** (e.g. high dose cyclophosphamide and high dose TBI (≥10Gy); high dose busulfan (12.8 mg/kg IV) + high dose cyclophosphamide)
- Patients receiving a manipulated graft (**in-vitro T-cell depletion**)
- Patients planned to receive a conditioning regimen with **alemtuzumab** (CAMPATH®)
- Patients planned to receive alloHCT with **cord blood cells**
- Patients planned to receive alloHCT from unrelated donor **with ≥ 3/10 HLA-mismatches**
- Patients receiving a large spectrum antibiotic at time of randomization for a serious infection or active uncontrolled infection
- Patients planned to receive **vedolizumab or abatacept** for GvHD prophylaxis
- **Contra-indication to allo-HSCT** (creatinine clearance <30 mL/min, bilirubin or amino-transferases abnormalities, cardiac ejection fraction less than 40%, pulmonary impairment with <50% lung carbon monoxide diffusing capacity (DLCO))
- Documented confirmed or suspected intestinal ischemia, toxic megacolon, bowel obstruction or gastrointestinal perforation, history of gastro-intestinal surgery in the past 3 months
- Any documented history of chronic digestive disease
- Patients with EBV-IgG negative serology
- Pregnancy and breastfeeding (urine or serum pregnancy test within 72 hours prior to randomization).

Study status

First patient dosed in November 2023

Active countries

NEXT

Conclusion

Herve Affagard
MaaT Pharma
CEO & Co-founder

Future milestones for MaaT013 in GvHD and MaaT033 in allo-HSCT

2024

MaaT013 (pooled enema)

GvHD | ARES P3 GI-ORR mid-24

MaaT033 (pooled capsule)

HSCT | PHOEBUS P2b First Safety Interim H2

2025

MaaT013 (pooled enema)

GvHD | Final Results (OS)

MaaT033 (pooled capsule)

HSCT | PHOEBUS P2b Second Safety Interim H2

2026

MaaT013 (pooled enema)

GvHD | Commercial launch

MaaT033 (pooled capsule)

HSCT | PHOEBUS Results

MaaT Pharma: A late-stage clinical biotech, leading the way in Microbiome therapies in oncology

LEADER	Listed on **Euronext (MAAT.PA)** global leader in the development of **Microbiome Ecosystem Therapies in oncology to enhance patient survival**
EXCELLENCE	Founded in **2014** | First Patient Treated in **2016** | **Pooling Pioneers** | First **FDA-Approved** Pooled Microbiota Trial | **7 Years Seed to Phase 3** | Factory Built in **Record 12 Months**
AI ENGINE	**Proprietary gutPrint® metagenomics research engine** driving product candidate generation by leveraging the data generated from MET-N products, to develop full synthetic microbiome MET-C programs using AI tools
MET-N	**Lead asset MaaT013 in Phase 3, available through Early Access Program** in aGvHD with results in 2024 and expected commercial launch in 2026 | **Second generation asset MaaT033** pooled capsule currently in **Phase 2b**
MET-C	**Ground-breaking co-culture donor independent MET-C platform** with first asset **MaaT034**, a full synthetic microbiome capsule **progressing towards IND in IO**
cGMP	**Largest European cGMP production facilities for microbiome** supporting our development endeavor
FINANCE	**Revenue** from **EAP of MaaT013 in aGVHD of 1.8m€ for the first three quarters of 2023** **Cash position of 31,7m€** with a **horizon** into the **second quarter of 2024**

Q&A

Herve Affagard
MaaT Pharma
CEO & Co-founder

Mohamad Mohty, MD, PhD
Professor of Hematology
Head of Hematology and Cellular Therapy Dpt.
Saint-Antoine Hospital
Paris, France

Florent Malard, MD, PhD
Professor of Hematology
Sorbonne University, INSERM
Hematology and Cellular Therapy Dpt.
Saint-Antoine Hospital
Paris, France