



# Corporate Update Positive Results for MaaT013 From Phase 2 Clinical Trial and Early Access Program

Webcast December, 13 2021

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# Speakers



**Hervé Affagard**  
**Co-founder and CEO**



**Dr. John Weinberg**  
**Chief Medical Officer**



**Pr. Mohamad Mohty**  
**Professor - Sorbonne University**  
**Head of the Clinical Hematology and**  
**Cellular Department - Saint-Antoine**  
**Hospital**



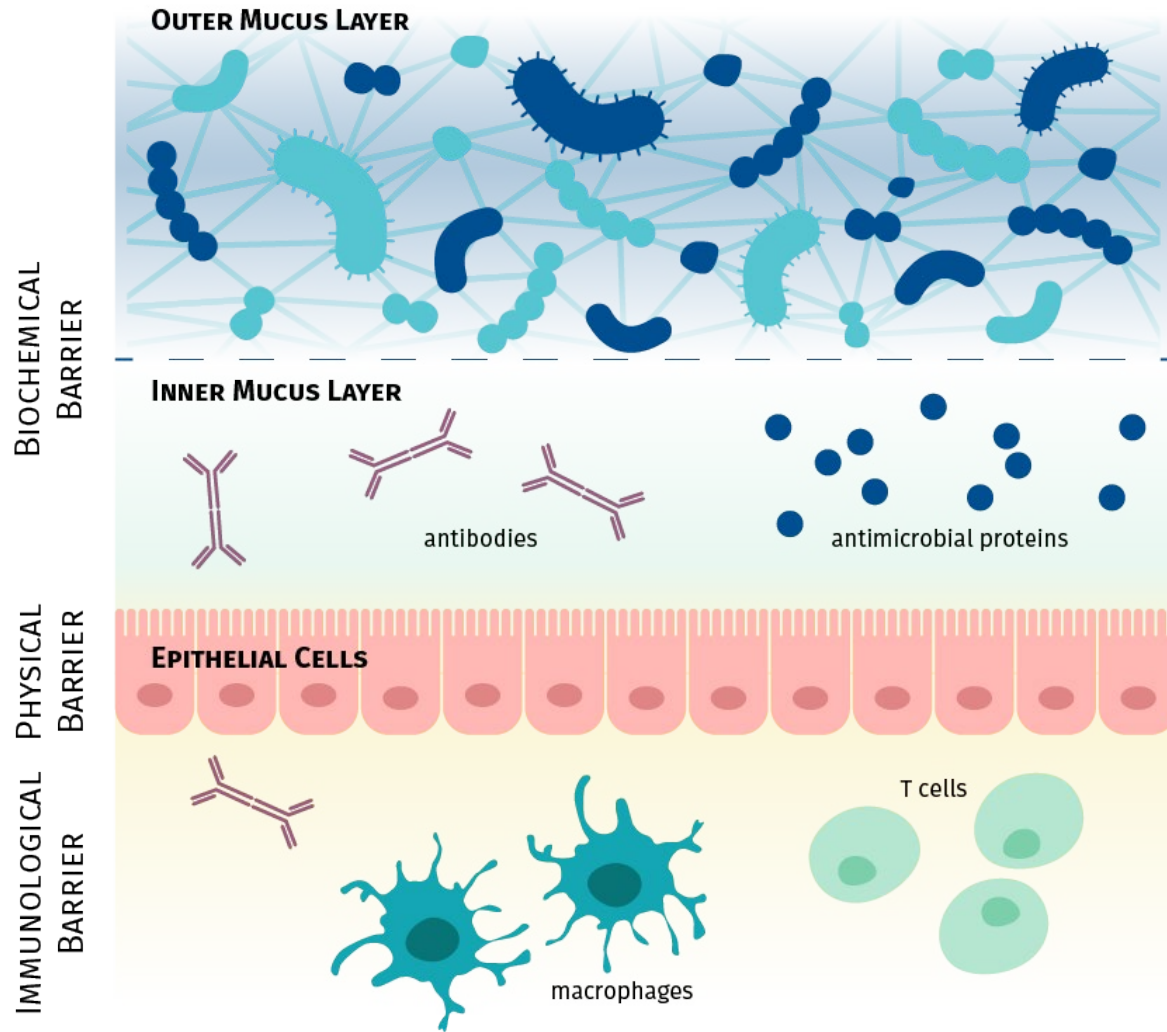


# Microbiome Ecosystem Therapies in Oncology



**Hervé Affagard**  
**Co-founder and CEO**

# Host – Microbiota Interactions are Critical for a Functional Immune System



Cross-section of a healthy gut

- A rich and diversified gut ecosystem actively modulates the immune system functionality
- A diversified microbiome contributes to the education and modulation of our immune system throughout life
- Bacterial richness and mucus layer prevent colonization by pathogens and improve gut barrier
- 80% of cellular host defense are localized in the gut (including innate and adaptive systems)

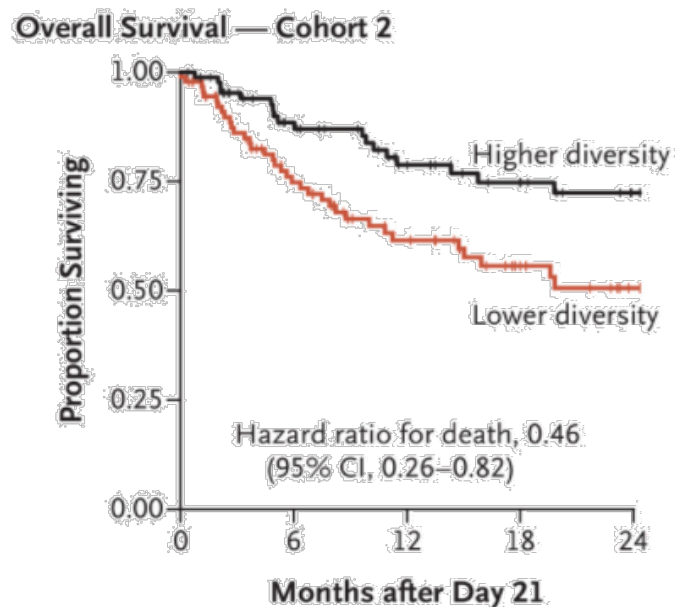


# Diversity matters!

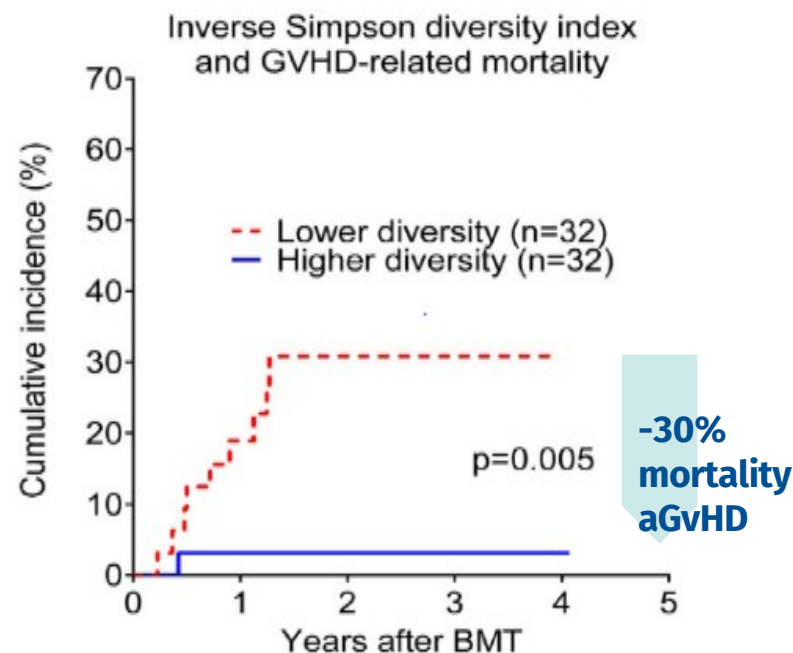
## Higher gut microbiome diversity is associated with ...

### Liquid Tumors

Higher survival rate in patients receiving allo-HSCT <sup>\*,1</sup>



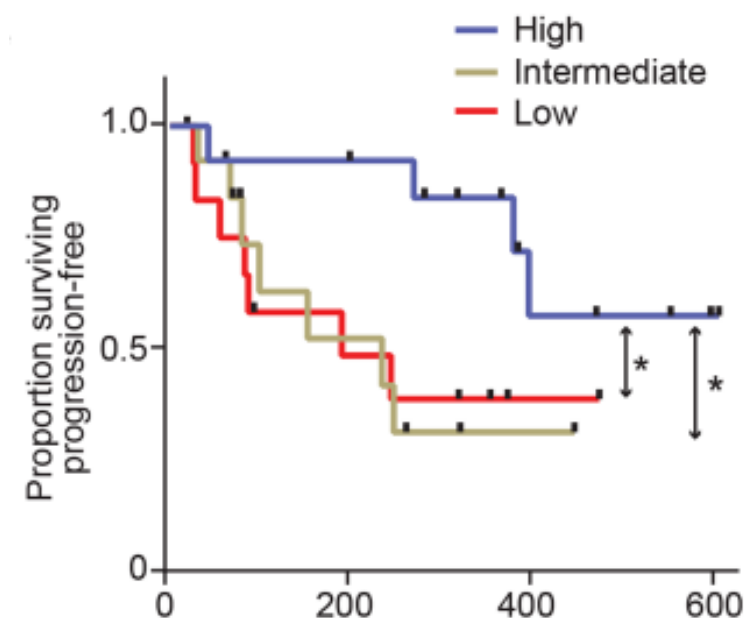
Lower incidence and lower mortality from aGvHD<sup>\*,2</sup>



MaaT Pharma MET Inverse Simpson (mean): 24

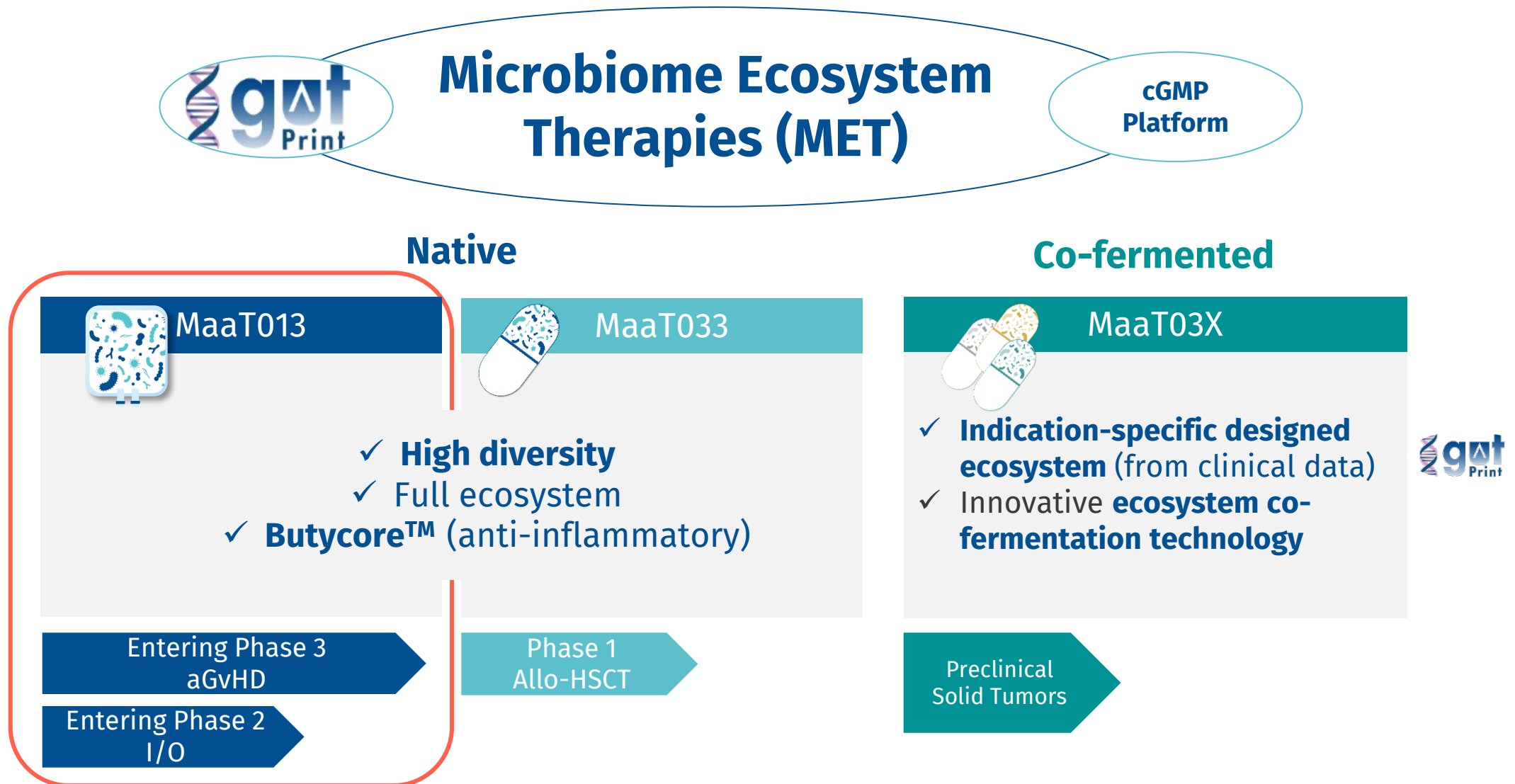
### Solid Tumors

Higher response rate to ICI\* in patients with metastatic melanoma<sup>3</sup>



\*allo-HSCT: allogeneic hematopoietic stem cell transplantation; aGvHD: acute Graft-vs-host-Disease; ICI: Immune Checkpoint Inhibitors  
<sup>1</sup>Peled, J.U. & al N Engl J Med 2020;382:822-34; <sup>2</sup>Ghani, 2021; <sup>3</sup>Jenq RR. et al, Biol Blood Marrow Transplant 21 (2015) 1373e1383; Pamer, Blood, 2014 ; Gopalakrishnan et al., Science, 2017, Routy et al, Science, 2018 ; Vetizou et al Science 2015;

# Cutting-edge platform generating a diversified product range



The logo for MaaT013, consisting of the letters 'Ma' in a light blue font and 'T' in a dark blue font, with 'âT' in a light blue font below them, all enclosed within a white circle.

# MaaT013 for the treatment of acute Graft-vs-host-Disease

Results from Phase 2 Clinical Trial and  
Early Access Program  
Presented at ASH 2021

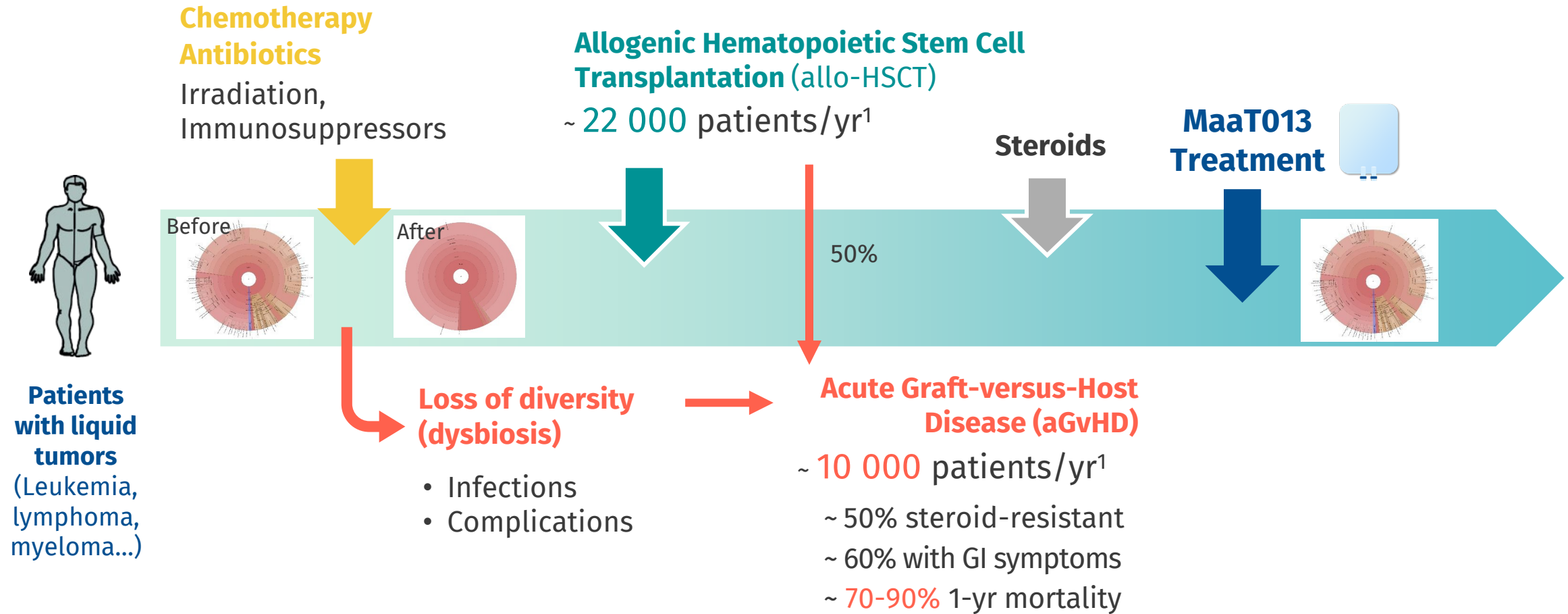


Pr. Mohamad Mohty



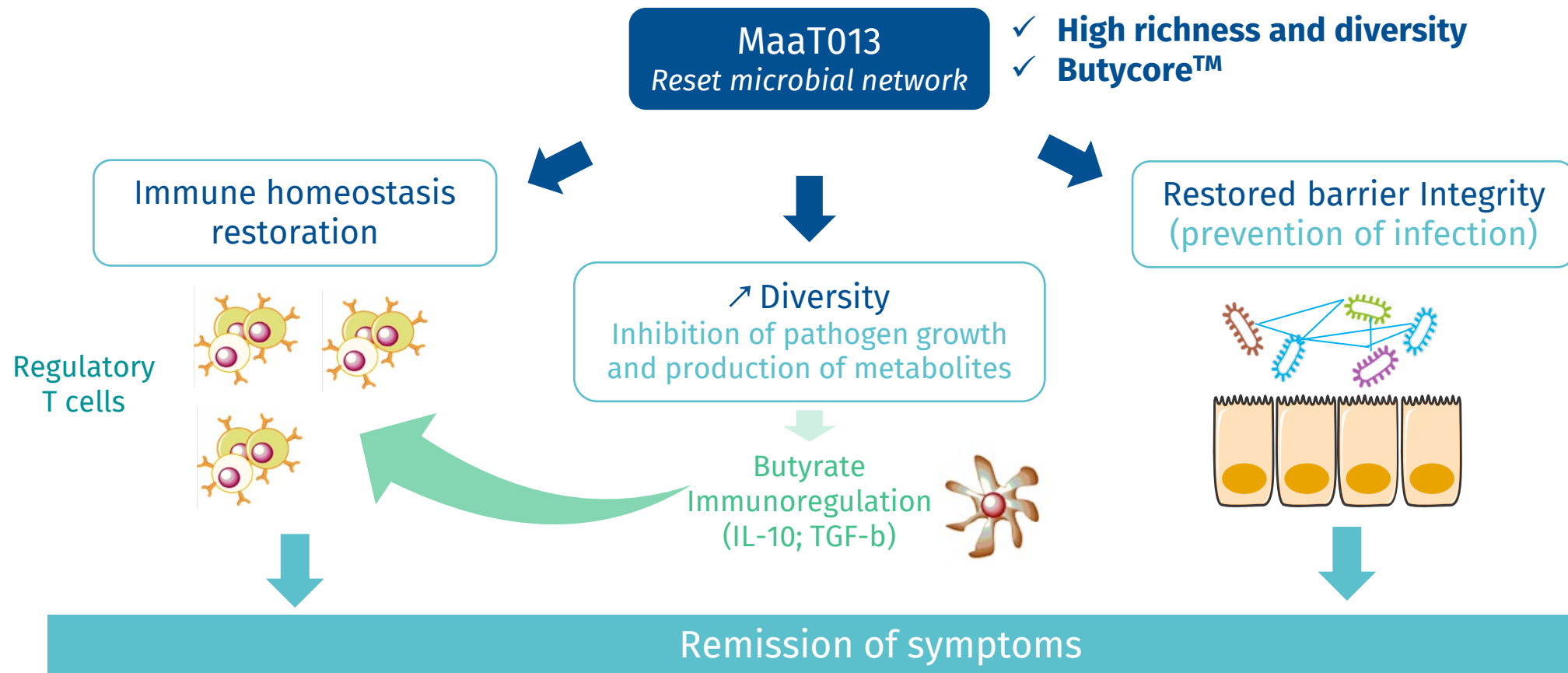
# An urgent medical need in acute Graft-vs-host-Disease (aGvHD)

Intestinal dysbiosis is associated with higher mortality in hemato-oncology



1. EU5 + US : (~ 20 500 primary procedures with an additional 7%-10% recurring)

# MaaT013 aims to restore interaction between the microbiome and the immune system to treat aGvHD



# Two complementary approaches generating data on MaaT013

## Phase 2 clinical trial - HERACLES

- Phase 2 clinical trial HERACLES (NCT03359980)
  - N=24 patients
  - 4 countries
- Gastro-intestinal aGvHD grade III-IV
- Steroid-refractory
- 3 doses of MaaT013 as a monothérapie over 2 weeks
- 2<sup>nd</sup> line of treatment
- Follow-up at 28 days (response) and after 12 months (overall survival)

## Early Access Program (ex « ATU »)

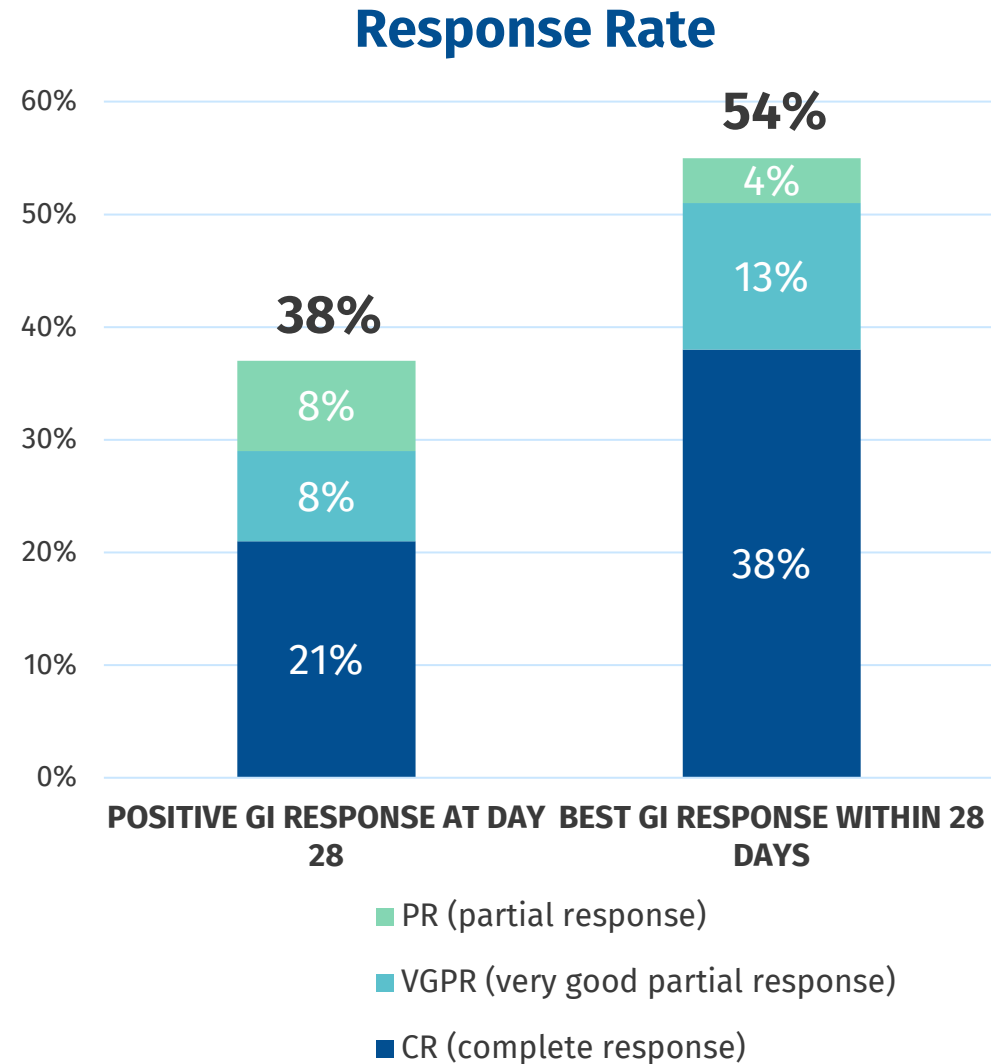
- Authorized par the French regulator (ANSM)
  - N=52 patients
  - France
- Gastro-intestinal aGvHD grade II-IV
- Steroid-refractory or steroid-dependent
- 3 doses of MaaT013 as monotherapy or in combination
- After 1 to 6 lines of treatment
- Follow-up at 28 days (response) and after 12 months (overall survival)

MaaT013 has received Orphan Drug Designation from **FDA and EMA**

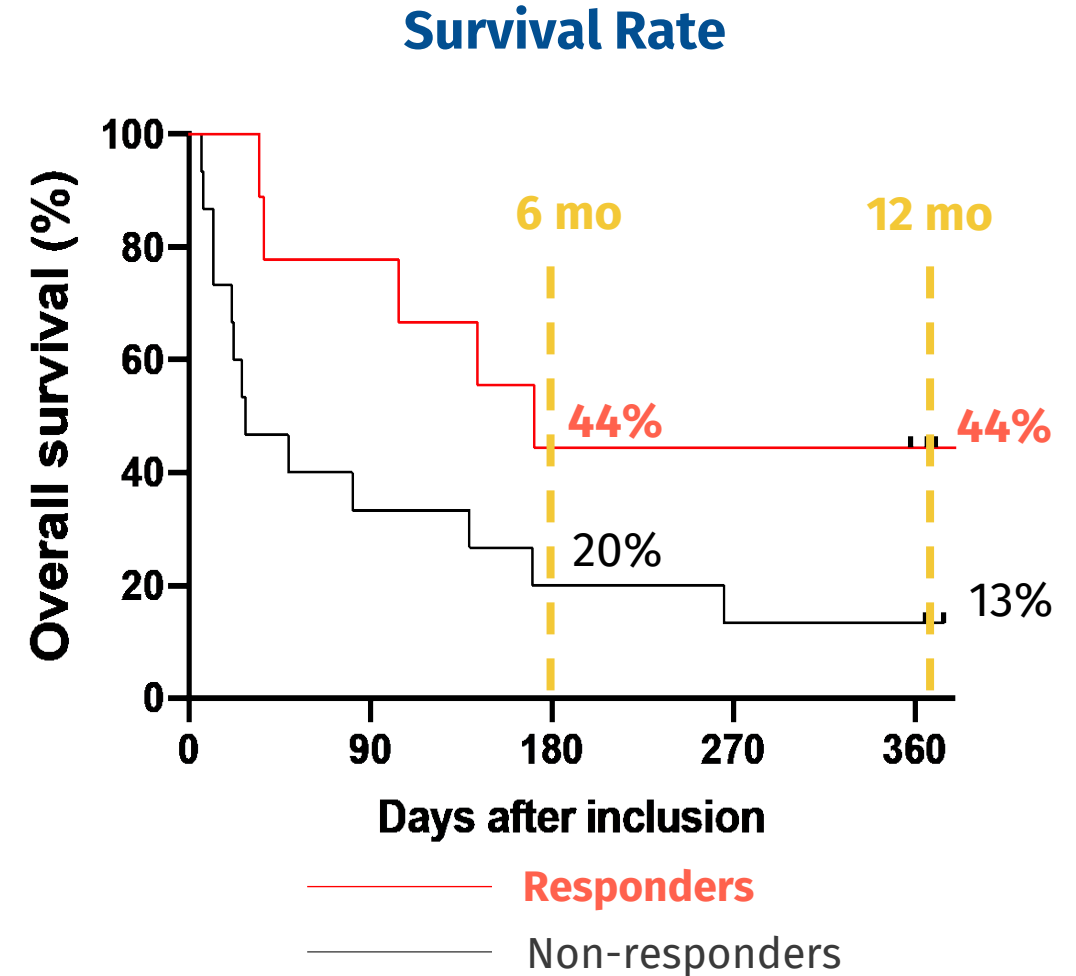
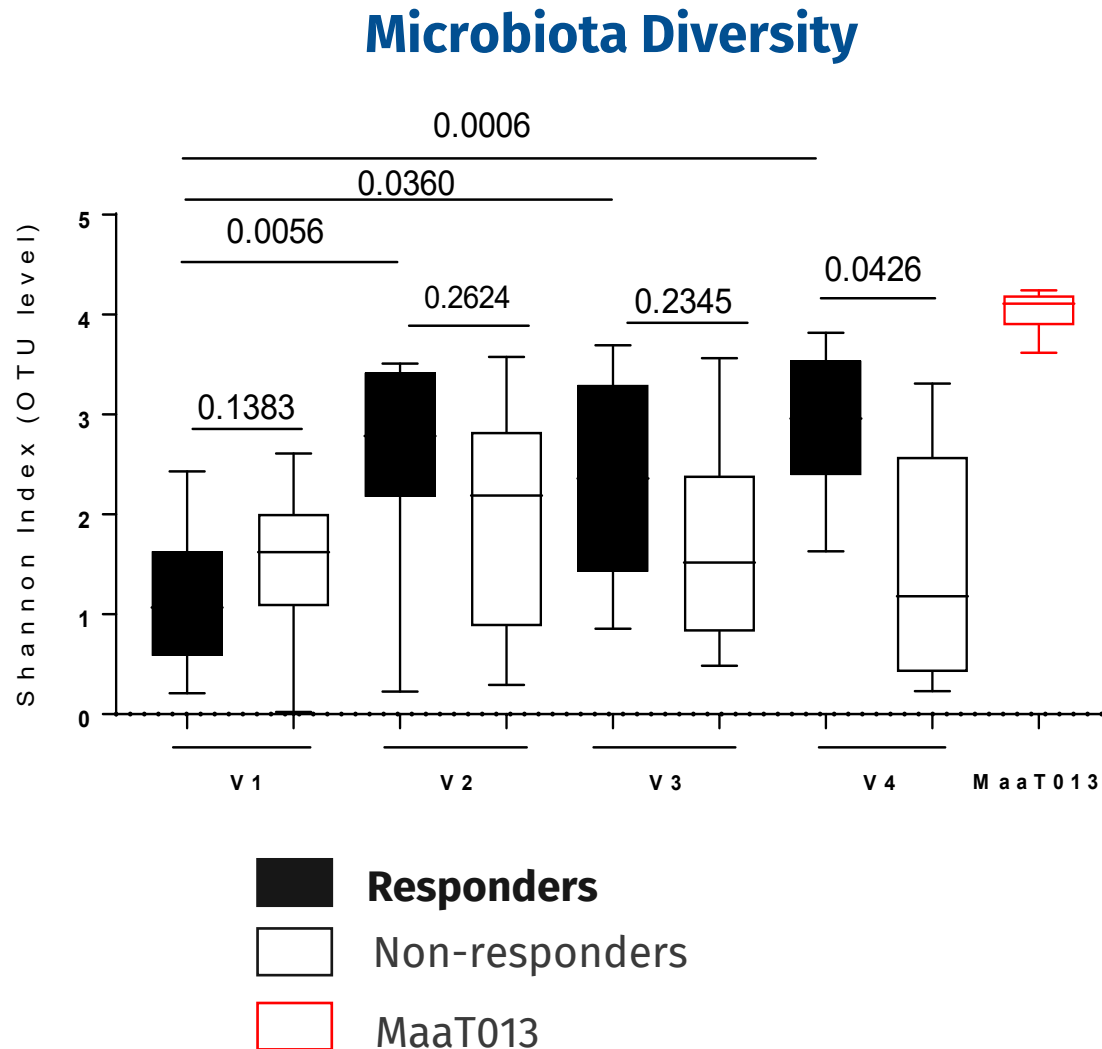
# HERACLES Phase 2 Clinical Trial

## Promising results in a very severe population (grade III-IV)

- 3 doses, 2<sup>nd</sup> line
- N=24 patients
  - 96% grade III, 4% grade IV
  - 100% steroid-resistant (SR)
  - Gastrointestinal (GI) predominant
- Very good safety and tolerability profile
  - 39 adverse events reported within 24 hours of administration

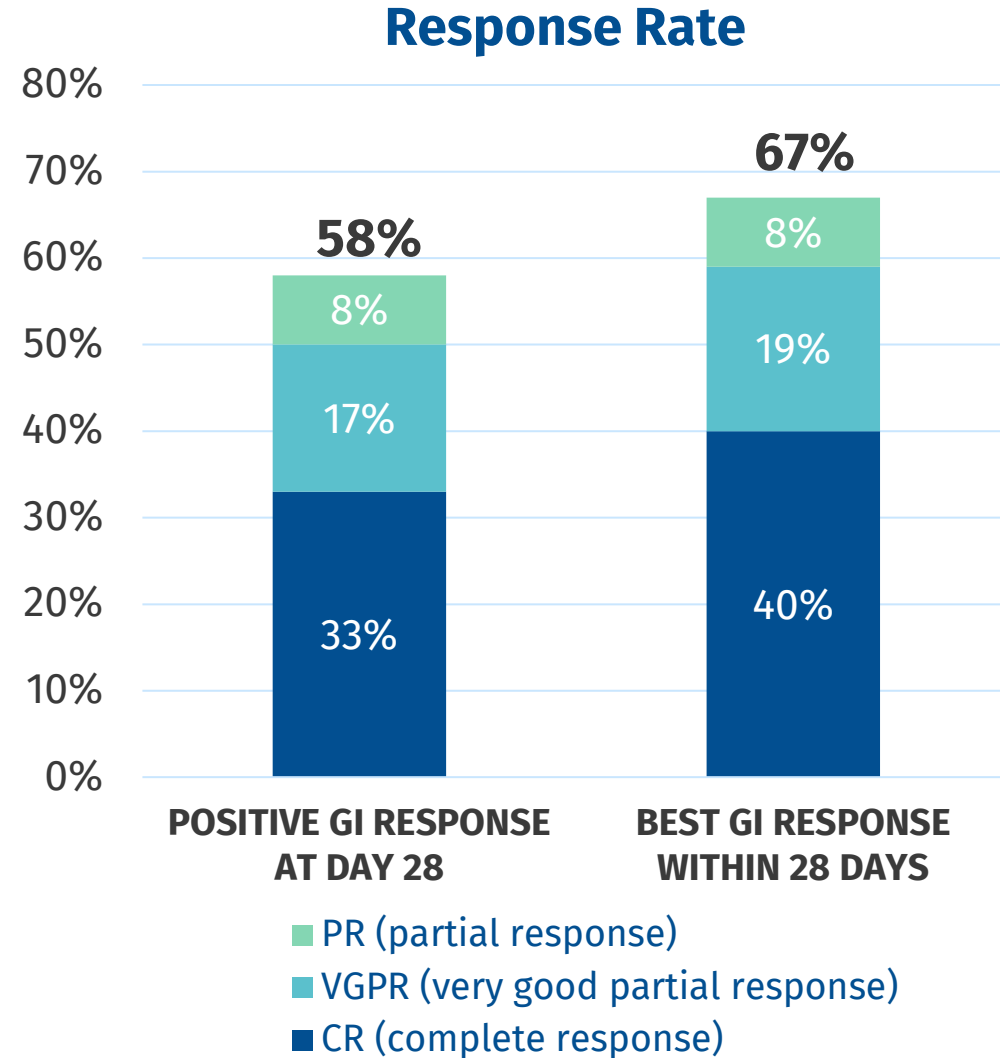


# HERACLES: MaaT013 increases Responders' microbiome diversity and their overall survival



# Early Access Program (EAP): A promising confirmation in a more diverse population

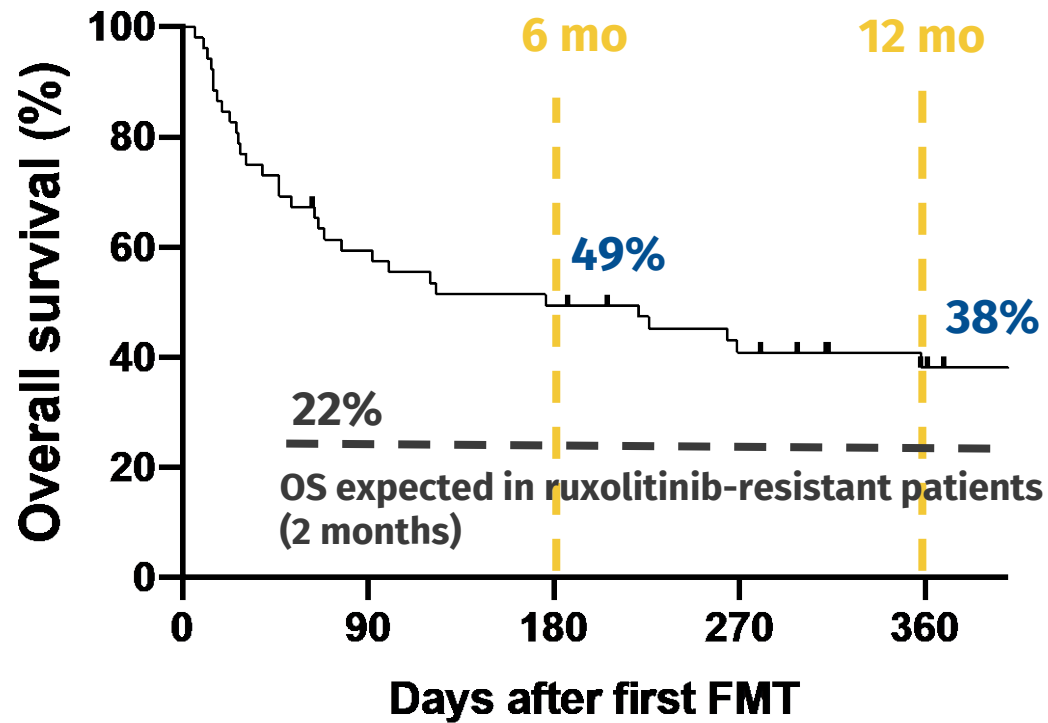
- 3 doses , 2<sup>nd</sup> to 7<sup>th</sup> line
- N=52 patients
  - 83% steroid-resistant (17% steroid-dependent)
  - 94% grade III, 6% grade II
  - All have gastrointestinal (GI) involvement
  - Previous treatments: 1-6 (median: 3)
    - 77% have received ruxolitinib previously
- Good tolerability and safety profile in a fragile population





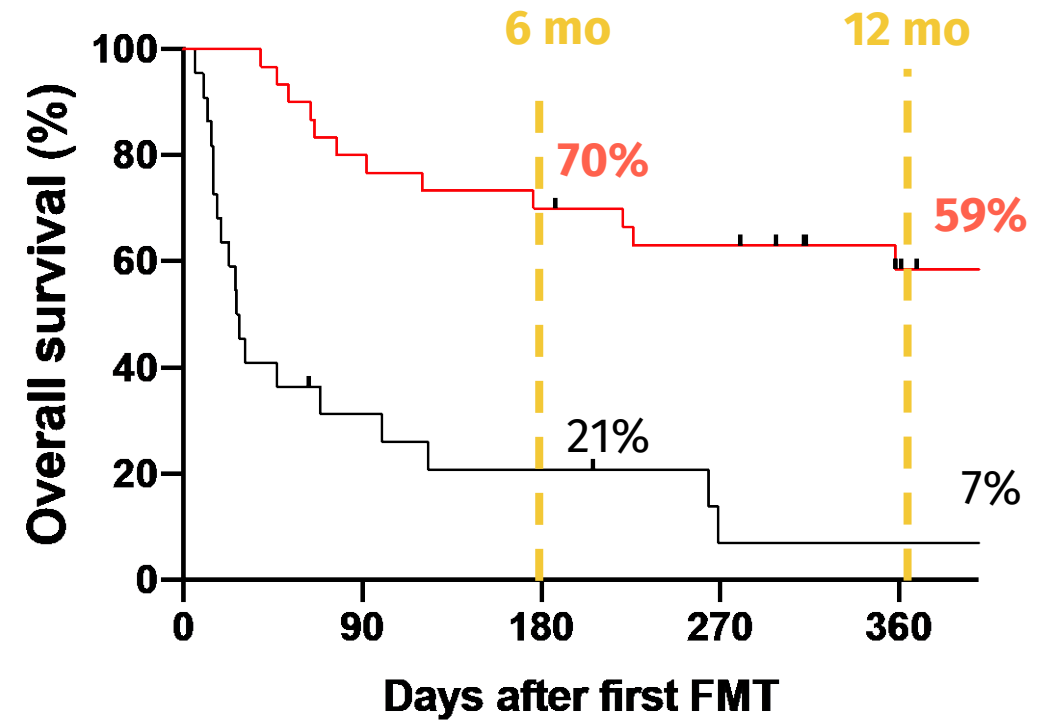
# Early Access Program (EAP): Very good overall survival results at 6 mo and 1 year

**Overall Survival**  
All patients



Median of follow-up in alive patients : 361 days (63-731)

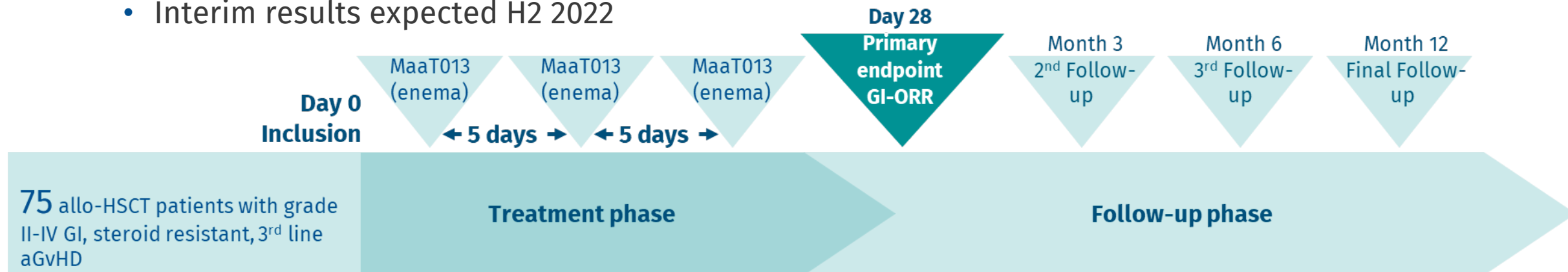
**Overall Survival**  
Responders vs. Non responders



— Responders  
— Non-Responders

# Next Step: ARES Phase 3 Clinical Trial

- Presented results support entering Phase 3, expected to be the last stage before registration
- **Positioned as 3<sup>rd</sup> line of treatment, to answer a strong medical need** (patients refractory to both steroids and ruxolitinib)
  - *No approved product in 3<sup>rd</sup> line to date*
- N=75 patients aGvHD grade II-IV
  - Pivotal single arm study
  - Interim results expected H2 2022





## Corporate Update



**Hervé Affagard**  
**Co-founder & CEO**

# Value-creating milestones expected in the next 12 months, including MaaT013 entering Phase 3 clinical trial

Hemato-oncology

aGvHD  
MaaT013  
(pooled enema)  
*FDA & EMA Orphan Drug Designation*

- ✓ Phase 3 ready to start in Europe
  - ✓ Authorization from 2 European countries received
    - MaaT Pharma will communicate at the inclusion of first patient (FPI)
    - Pursuit of Early Access Program in France
  - Extension to US sites expected H2 2022 subject to IND approval by the FDA

Complications post  
allo-HSCT  
MaaT033  
(pooled capsule)

- ✓ Phase 1b ongoing
  - Results expected S1 2022
- Pivotal Phase 2/3 expected to start end of 2022

Immuno-oncology

Melanoma  
Checkpoint Inhibitors  
Potentiation  
MaaT013  
(pooled enema)

- ✓ Phase 2a ready to start in France (Sponsor AP-HP)<sup>1</sup>
  - ✓ Authorization from ANSM received



Solid Tumor  
MaaT03X  
(co-fermented capsule)

- ✓ Preclinical study ongoing
  - First clinical study expected H1 2023
  - Public grant of 4.26M€ received (France Relance-PIA4)

<sup>1</sup> Investigator sponsored trial where MaaT Pharma supplies the drugs and performs the microbiome profiling using its gutPrint® platform

# Key differentiators of MaaT Pharma in the microbiome field

## Full ecosystem approach

Pioneering a full ecosystem approach leveraging the full functionality of the microbiome

## Manufacturing versatility

**Capacity to industrialize manufacturing processes (cGMP)** for native and co-fermented products

## Oncology focus

**Focus on high unmet need diseases** in hemato-oncology and solid tumor spaces

## Established proof of concept

Validated approach in **clinical trials authorized by multiple regulatory authorities**

MaaT



# Ma rôT

Q&A



Hervé Affagard

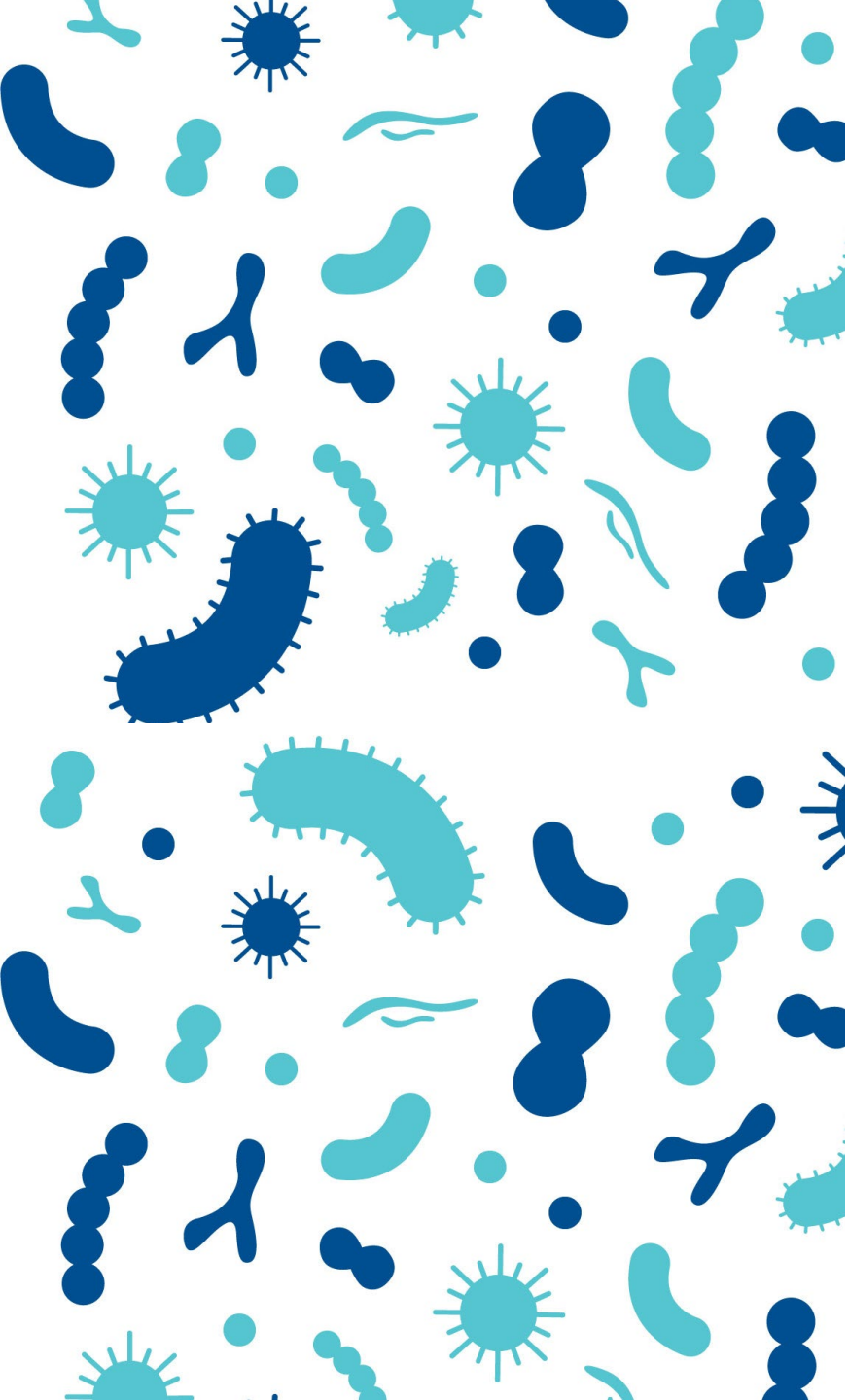


Prof. Mohamad Mohty



Dr. John Weinberg





THANK  
YOU