

64th **ASH Annual Meeting**: December 10-13, 2022

# Investor webcast - ASH 2022





# Introduction & Opening remarks



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### Hervé Affagard

**CEO & co-founder** 

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#### Agenda

Introduction & opening remarks

Hervé Affagard - CEO and co-founder



Pooled MET for refractory gastrointestinal acute graft-versus-host disease: results from the Early Access Program in France **Pr. Mohamad Mohty** – Professor, Sorbonne University and Head of the Clinical Hematology and Cellular Department, Saint-Antoine Hospital

Restoration of gut microbiota diversity with oral MET MaaT033 in acute myeloid leukemia patients after intensive chemotherapy: the phase 1b CIMON trial

**Pr. Florent Malard, M.D** – Professor of Hematology, Saint Antoine Hospital (AP-HP) and Associate Professor, Sorbonne University

Expected newsflow & ending remarks

Hervé Affagard - CEO and co-founder









# Pioneering innovative microbiome therapy for the benefit of millions of patients fighting cancer



Listed on Euronext (MAAT)

**Differentiated approach** pioneering **Microbiome Ecosystem Therapies** to address **hematological malignancies and oncology,** 

Multi-asset clinical and preclinical pipeline with lead asset in Phase III in aGvHD and near-term, value-creating catalysts

**Proprietary gutPrint® metagenomics technology platform** driving product candidate generation

**European cGMP production facilities** supporting versatile product range and optimized positioning

50 Employees incl. >30% with a PhD 3 Products in development 13 Patent families protection until 2036-2041 in all major markets



Raised to date (€69M in equity) 200+ Patients safely treated in Europe (+140 w/

MaaT013)

December 12, 2022

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





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

cellular host defense localized in the gut

#### Cross-section of a healthy gut

#### Diversity matters! Higher gut microbiome diversity is associated with ...





MaaT Pharma MET Inverse Simpson (mean): 24

<sup>\*</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; Jenq RR. et al, Biol Blood Marrow Transplant 21 (2015) 1373e1383; Pamer, Blood, 2014 ; <sup>3</sup>Gopalakrishnan et al., Science, 2017, see also Routy et al, Science, 2018 ; Vetizou et al Science 2015;

December 12, 2022

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CLETY OF AREKICAN SOLUTION

MaaT Pharma's Microbiome Ecosystem Therapy (MET) platform has generated a diverse line of product candidates



<sup>1</sup> Butycore: Group of 15 different genera known to produce short-chain fatty acids with anti-inflammatory properties <sup>2</sup> Sponsored by AP-HP

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# Looking ahead: addressing growing market opportunities with severe medical need





### In 2022, MaaT Pharma delivered on its objectives

		Clinical program	Milestones announced at IPO (Nov 2021)	Status	Update as of Dec. 2022	
Onco-hematology		<b>MaaT013 (pooled enema)</b> FDA & EMA Orphan Drug Designation	Launch of the first Phase 3 trial in oncology in the world		<ul> <li>Ongoing Phase 3 trial (n=75) in 6 countries in Europe</li> <li>Ongoing EAP in France, expansion to other EU countries</li> </ul>	
	I	<b>MaaT033 (pooled capsule)</b> Post allo HSCT	Completion of Phase 1b trial and positive preliminary safety and engraftment data		Preparation of Phase 2b trial in Europe	
Immuno-oncology		<b>MaaT013 (pooled enema)</b> Improving ICI responses in metastatic melanoma	Launch of Phase 2 trial* - POC * Sponsored by AP-HP		Ongoing trial in France	
	<b>S</b>	MaaT03X (fermented capsule) Undisclosed indications	Preclinical activities to enter clinical development in 2023	$\checkmark$	Ongoing preclinical studies and scaling-up of CMC	
cGMP production	Skyepharma	Increasing cGMP production capacities	Partnership with Skyepharma to build the largest exclusive Microbiome Ecosystem Therapies facility in Europe		Preparation to transfer R&D and manufacturing activities Start of construction in July 2022	

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# The ASH (American Society of Hematology) annual meeting is the world-leading event in malignant and non-malignant hematology



- The annual meeting is organized by the American Society of Hematology
- It is renowned for presenting the top hematology research and sharing knowledge on how to improve patient management and care strategies.
- In 2021, 29 800+ participants<sup>1</sup> attended the event (on-site & virtual)
- ASH Abstracts are published in Blood, a peer-reviewed, open-access, online journal and the flagship journal of the American Society of Hematology (#2 behind Nature Hematology).

#### MaaT Pharma at ASH:

- $\checkmark$  3<sup>rd</sup> year in a row selected for an <u>oral</u> presentation
- ✓ 6<sup>th</sup> year in a row that the Company's clinical data are selected for presentation ( oral or poster format)





#### MaaT013, a novel Microbiome Ecosystem Therapy™ to treat acute Graft-vs-host-Disease



#### Hervé Affagard

**CEO & co-founder** 



# Generating data for MaaT013, our lead asset for acute hospital use to treat acute Graft-versus-Host Disease, via 2 channels

#### ✓ Completed Phase 2 trial in 2<sup>nd</sup>-line SR, GI-aGvHD (n=24)

#### Ongoing Phase 3 in 3<sup>rd</sup> line SR/SD, ruxolitinib-refractory GI-aGvHD

- Pivotal single-arm trial of MaaT013 as 3rd line treatment in n=75 GI-aGvHD patients
- Ongoing in 6 countries in Europe
- FDA Clinical hold (CH) as of Aug 2022: Multiple CMC and clinical questions have been resolved, but CH maintained → MaaT Pharma is in active discussion wit the FDA.

#### Ongoing Early Access Program

- Since 2018, and as approved by ANSM, French patients may benefit from early access to MaaT013 as salvage therapy, mainly for the treatment of acute Graft-vs-host-Disease.
- As of October 2022, the Company has treated 116 patients in the EAP program. Today, we will share data for 81 patients included in this program.
- To support the EAP, the Company has strengthened its supply chain and manufacturing capacities, enabling the delivery of MaaT013 to 24 European hospital transplant centers to date.

#### Targeted market: > 2,000 patients in Europe (5), US and Japan







#### Pooled MET for refractory gastrointestinal acute graft-versus-host disease: results from the Early Access Program in France



#### Pr. Mohamad Mohty

Professor & Head of the Clinical Hematology and Cellular Department - Saint-Antoine Hospital





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

SOCIETY OF AREM

Intestinal dysbiosis is associated with higher mortality in haemato-oncology



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



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





MaaT013 aGvHD

# MaaT013, a novel agent to restore the microbiome to treat gastro-intestinal aGVHD (GI-aGvHD)















Administration 3 doses administered via enema within 2 weeks

Characteristics Pooled microbiota: a high-richness, high-diversity, full ecosystem, containing Butycore™, 24 months stability at -80°C

#### **Available Clinical Data**

 ✓ HERACLES Phase 2 Clinical Trial, n=24,
 ✓ Early Access Program, data on n=81, presented today Ongoing (116 patients treated as of Oct. 2022)

#### Efficacy evaluation (GI ORR at Day28)

Complete response, Very Good Partial Response, Partial Response

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### Early Access Program in France



- Authorized by the French regulator (ANSM); governing protocol for use
  - Data from 81 patients treated from July 2018 to May 2022
  - 17 French sites
- Patients' characteristics:
  - Adult patients with GI-aGvHD grade II-IV
  - Resistance to, or dependence on, corticosteroids (CS)
  - After 1-6 lines of treatment; median 2
  - ORR at 28 days, and survival at 12-month

Characteristics	All patients (N=81)					
Steroid status						
<ul> <li>Steroid resistance</li> </ul>	68 (84%)					
$\circ~$ Steroid dependence	13 (16%)					
Type of aGvHD						
○ Classical	62 (77%)					
$\circ$ Late onset	12 (15%)					
<ul> <li>Overlap syndrome</li> </ul>	7 (9%)					
aGvHD grade at the time of request (as per Harris, 2016)						
0 I	0					
0 <b>II</b>	9 (11%)					
o III	41 (51%)					
o IV	31 (38%)					
GvHD organ involvement at inclusion						
○ GI only	48 (59%)					
$\circ$ GI + skin	<b>19 (23%)</b>					
○ GI + liver	3 (4%)					
$\circ$ GI + skin + liver	3 (4%)					
$_{\odot}$ Missing data for skin and liver	8 (10%)					



### GI-GvHD response (all patients)

PR

CR



Abbreviations: CR, complete response; VGPR, very good partial response; PR, partial response; ORR, overall response rate; GI, gastro-intestinal

		Grade II	Grad	de II	Grade IV	
	Response, N (%)	GI Stage 1 N=9	GI Stage 2 N=18	GI Stage 3 N=23	GI Stage 4 N=31	Total N=81
PR	GI-ORR	8 (89%)	12 (67%)	15 (65%)	10 (32%)	45 (56%)
VGPR CR	CR	7 (78%)	10 (56%)	10 (43%)	3 (10%)	30 (37%)
	VGPR	0	2 (11%)	3 (13%)	6 (19%)	11 (14%)
	PR	1 (11%)	0	2 (9%)	1 (3%)	4 (5%)
	Response, N (%)	GI stage 1 N=8	GI Stage 2 N=18	GI Stage 3 N=22	GI Stage 4 N=30	Total N=78*
	ORR	7 (88%)	11 (61%)	11 (50%)	9 (30%)	38 (49%)
	CR	6 (75%)	9 (50%)	6 (27%)	3 (10%)	24 (31%)
	VGPR	0	2 (11%)	4 (18%)	5 (17%)	11 (14%)
ponse; estinal	PR	1 (13%)	0	1 (5%)	1 (3%)	3 (4%)

\* Missing skin and liver data at Day 28 for n=3 patients

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### Overall survival (all patients, n=81)





#### Clinical response to MaaT013 translates to increased overall survival

Abbreviations: CR, complete response; VGPR, very good partial response; PR, partial response



### GVHD response in steroid- dependent (SD) vs. steroidrefractory (SR) patients







Abbreviations:

CR, complete response; VGPR, very good partial response; PR, partial response; ORR, overall response rate; GI, gastro-intestinal; SR-aGVHD, steroid-refractory acute graft-versus-host disease; SD-aGVHD, steroid-dependent acute graft-versus host disease





### GVHD response in the ruxolitinib-refractory patients



Abbreviations:

CR, complete response; VGPR, very good partial response; PR, partial response; ORR, overall response rate; GI, gastro-intestinal



# Overall survival in steroid- and ruxolitinib- refractory patients treated as 3rd line (n=31)



**Clinical response to MaaT013 translates to increased overall survival** -> this is the patients' population currently included in Phase 3 ongoing trial

Abbreviations: CR, complete response; VGPR, very good partial response; PR, partial response

MaaT013 aGvHD

#### Safety profile

- Overall safety is very good compared to historical data in such heavily pre-treated and fragile population
- 20 pharmacovigilance cases reported in 18 patients
  - 11 bacteremia / sepsis
  - 2 C. difficile colitis
  - 1 E. coli osteoarthritis
  - 1 presence of Geotrichum silvicola in stools
  - 1 Pseudomonas aeruginosa sinusitis
  - 1 appearance of air bubbles in the mesorectum
  - 1 respiratory distress
- No report of pathogen transmission
- Only 2 cases of non-pathogenic commensal bacteria associated with infectious events





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Conclusions

- MaaT013 is a highly effective therapy for SR- and SD-GI- aGVHD
  - D28: GI-ORR: 56%
  - D28: ORR: 49%
- Excellent responses in the ruxolitinib-refractory patients (MaaT013 as 3rd line)
  - D28: GI-ORR: 65%
- Clinical responses translated to increased overall survival in responding patients
- Overall safety is very good







Further investigation currently ongoing in a phase 3 trial targeting 3<sup>rd</sup> line in patients with GI aGvHD who are refractory to both steroids and ruxolitinib



### ARES: Phase 3 study of MaaT013 as 3<sup>rd</sup>-line therapy in GI-aGvHD



- Pivotal single-arm study of MaaT013
- Primary endpoint: GI response at Day 28
- First patient included in March 2022
- Sites initiated in Europe: France, Germany, Spain, Belgium and Austria
- Next steps:
  - Expected to further expand in EU
  - Interim Safety & Efficacy Review in H1 2023

#### Abbreviations:

- D: Day, M: Month, EOT: End of treatment
- SR-GI-aGvHD: Steroid-refractory gastro-intestinal acute Graftversus-Host Disease
- ORR: Overall Response Rate; CR: Complete Response; VGPR: Very Good Partial Response; PR: Partial Response

#### ClinicalTrials.gov Identifier: NCT04769895



# THANK YOU











#### Hervé Affagard

**CEO & co-founder** 

Restoration of the gut microbiome has shown potential in improving survival for patients receiving allogeneic HSCT







- Allo-HSCT is often the only curative approach for patients with hematological malignancies such as leukemia, but the procedure presents significant risks, such as infections and GvHD
- Literature has demonstrated that higher gut microbiome diversity is associated with a significant reduction in the risk of infectionand GvHD-related mortality following allogeneic HSCT <sup>1,2</sup>
- MaaT033 is being developed as an adjunctive and maintenance therapy to allo-HSCT, with the aim of improving patients' survival.



#### MaaT033 opens new market perspectives





#### Approximately 22,500 procedures/year

<sup>1</sup>EBMT aHCT Survey, 2017 (published in Bone Marrow Transplantation (2019) 54:1575–1585), Global Data 2020

#### Hematological Malignancy Patients Receiving Allo-HSCT<sup>1</sup>



*AML* : acute myeloid leukemia; *ALL* : acute lymphoblastic leukemia ; *MDS* : myelodysplastic syndrome; *MPN* : myeloproliferative neoplasms ; *CML*: chronic myeloid leukemia ; *CLL* : chronic lymphocytic leukemia ; *HL*: Hodgkin's Lymphoma ; *NHL*: Non Hodgkin Lymphoma





#### Restoration of gut microbiota diversity with oral MET MaaT033 in acute myeloid leukemia patients after intensive chemotherapy: the phase 1b CIMON trial



#### Pr. Florent Malard

Professor of Hematology, Saint Antoine Hospital (AP-HP) and Associate Professor, Sorbonne University



# MaaT033: An **optimized oral capsule** to restore and maintain a healthy gut microbiome in patients with severe dysbiosis



MaaT033 Allo-HSCT MaaT033 is intended to be an **adjunctive and maintenance therapy** for patients with hematological malignancies receiving allo-HSCT



MaaT033

Allo-HSCT

MaaT033's MOA aims to restore and protect the gut microbiota, to **improve survival** in allo-HSCT patients through the prevention of infections and aGvHD





#### **Remission of symptoms**





Cohort 5 (n=6)

Cohort 4 (n=6)

CIMON: a phase 1b open-label, dose finding study (21 patients)

**CIMON study design** 

Phase I, open-label, single-arm 6 investigational sites in France

MaaT033 Allo-HSCT

Not performed, due to sufficient data from Cohort 1-4

💎 / day, 2 weeks



### Gut microbiota analysis



- MaaT033 induces an increased microbiota richness at OTUs level
- MaaT033 displays a strong and persistent bacterial engraftment , higher in <u>cohort 3</u> and <u>cohort 4 (3 capsules per day)</u> compared to cohorts 1 and 2 (1 capsule per week / 1 capsule per day).
- MaaT033 bacterial engraftment is inversely correlated with patients' baseline microbiota richness



#### Host parameters analysis



MaaT033 engraftment correlates with anti-inflammatory markers (TGF-β and fecal SCFA) levels and inversely correlates with inflammatory markers (IL2 and neopterin)



December 12, 2022

### MaaT033 treatment is safe: good tolerance

- MaaT033 Allo-HSCT
- 4 SAEs reported in 4 patients: only one considered as possibly related by the investigator

Event	Cohort 1 (N=3) n (%)	Cohort 2 (N=6) n (%)	Cohort 3 (N=6) n (%)	Cohort 4 (N=6) n (%)	Total (N=21) n (%)
Febrile neutropenia	0	1 (17%)	0	0	1 (5%)
Neutropenic colitis	0	0	1 (17%)	0	1 (5%)
Diarrhoea infectious	0	0	0	1 (17%)	1 (5%)
Hyperkalaemia	0	1 (17%)	0	0	1 (5%)

- The SAE infectious diarrhea with enteropathogenic E. coli (EPEC) started 3 days after MaaT033 treatment initiation.
- EPEC strain not found in MaaT033 batch (genome sequencing) nor in patient's feces before MaaT033 administration
- Absence of pillbox contamination verified by PCR => Relationship to MaaT033 was unlikely, although it could not be formally excluded.



# Next step: Randomized clinical trial evaluating MaaT033 to prevent complications of allo-HSCT



- 389 patients in a randomized, double-blind, placebo-controlled study
- Primary endpoint: efficacy of MaaT033 in improving overall survival at 12 months
- Evaluate safety and tolerability before and after allo-HSCT
- Evaluate engraftment of MaaT033 and activity in preventing allo-HSCT complications (infections, GvHD)



### Conclusion

Safe & effective

MaaT033 appears to be **safe and effective for gut microbiota restoration in AML patients** receiving induction chemotherapy and antibiotics.

After IC in immunocompromised AML patients: good tolerance, minimal toxicity after treatments and postneutropenia.



3 MaaT033 capsules per day for 1 week induce an increase in microbiota richness and an effective and persistent MaaT033 bacterial engraftment in AML patients. Phase IIb trial

A Phase IIb trial is planned to evaluate MaaT033 as an adjunctive and maintenance treatment in patients with hematological malignancies receiving allogeneic hematopoietic stem cell transplantation.



MaaT033 Allo-HS<u>CT</u>



# THANK YOU







# Expected newsflow & ending remarks



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#### Hervé Affagard

CEO & co-founder



#### Key take-away messages

- MaaT013:
  - New positive data generated from EAP program shows that MaaT013 has a good overall safety and is a highly-effective therapy for SR- and SD-GI- aGVHD
  - Further investigation in SR-aGvHD and SD-aGvHD currently ongoing in a Phase 3 trial in Europe
- MaaT033:
  - MaaT033 appears to be safe and effective for gut microbiota restoration in patients with acute myeloid leukemia receiving induction chemotherapy and antibiotics.
  - Phase 2b trial is planned to evaluate MaaT033 as an adjunctive and maintenance therapy to improve survival in patients receiving allo-HSCT.

MaaT Pharma's hemato-oncology programs are generating promising clinical data to improve patients' survival.

Abbreviations: SR-aGVHD, steroid-refractory acute graft-versus-host disease; SD-aGVHD, steroid-dependent acute graft-versus-host disease

# Value-creating milestones expected in the next 12 months, including MaaT033 entering Phase 2b clinical trial



Hemato-oncology	aGvHD MaaT013 (pooled enema) FDA & EMA Orphan Drug Designation	<ul> <li>✓ Ongoing Phase 3 in Europe</li> <li>European Phase 3 interim results H1 2023</li> <li>ORR results expected H2 2023</li> <li>Pursuit of Early Access Program in France and Europe</li> </ul>				
	Improvement of survival post allo-HSCT MaaT033 (pooled capsule)	• Pivotal Phase 2b expected to start in H1 2023				
-oncology	Melanoma Checkpoint Inhibitors Potentiation MaaT013 (pooled enema)	<ul> <li>✓ Ongoing POC Phase 2a in France (Sponsor AP-HP)<sup>1</sup></li> <li>Internal data readout H1 2023</li> </ul>	ASSISTANCE DE HÔPITAUX DE PARIS GUSTAVE/ BRAND PARIS			
Immuno	Solid Tumor MaaT03X (co-cultured capsule)	<ul> <li>✓ Preclinical study ongoing</li> <li>First clinical study expected in 2023</li> </ul>				



### **Opening of MaaT Pharma's MET facility,** the largest one in Europe, expected in 2023





A dedicated 1,500 square meter site (which could be doubled). Expected to be operational in H2 2023.



Designed to support

- Clinical and commercial manufacturing of MaaT013 and MaaT033
- R&D and clinical manufacturing of MaaT03X product range



In-house and outsourced expertise combined:



- R&D & production .
- team .
- proprietary equipment •

Control of oversight of R&D, clinical and commercial production



- CGMP compliant building .
- product quality standards, regulatory affairs,
- certification, ٠
- large-scale production.





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### Key differentiators of MaaT Pharma in the microbiome field



# Full ecosystem approach Pioneering a full ecosystem approach leveraging the full functionality of the microbiome **Oncology focus** Focus on high unmet need diseases in hemato-oncology and solid tumor

#### Manufacturing versatility

Industrialization of manufacturing processes (cGMP) for native and co-cultured products

spaces

**Established proof of** concept

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



# Q&A session



# THANK YOU

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December, 12<sup>th</sup>, 2022- ASH Investor webcast