

MaaT Pharma

Announcing Positive Topline Results from Pivotal Phase 3 ARES Study with MaaT013 in aGvHD

Comments & Perspectives

January 9th, 2025



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Management Team



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) Groundbreaking Phase 3 Data – Gianfranco Pittari

The Expert Perspective – Prof. Mohamad Mohty, MD, Sorbonne University and Saint Antoine Hospital (AP-HP), Paris, France

Strategic Implications and Market Opportunities – Herve Affagard

Newsflow and Funding Opportunities – Eric Soyer

Q&A - All

Closing remarks - Herve Affagard / Eric Soyer



Introduction

Hervé Affagard

MaaT013 in aGvHD: Primary Endpoint of Phase 3 Study Achieved Registration in Europe Spearheading Microbiome Therapies in Oncology



<u>Now available:</u> Phase 3 Data in aGvHD from the ARES study

\rightarrow	Primary endpoint: unprecedented,
	GI-ORR [*] of 62% in patients having
	previously received steroids and
	ruxolitinib

- High response rate leading to prolonged survival, highlighting MaaT013's potential to overcome the short-term mortality of third-line GI-aGvHD
- Company anticipates MAA submission in Europe, in mid-2025, earlier than initially planned



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

- Cash position of 27m€ as of September 30, 2024. Cash runway extends into Q2/2025
- Potential 750m€ yearly peak sales
 Hemato-Onco franchise for partnering:
 250m€ for MaaT013 in GvHD and 500m€
 for MaaT033 in allo-HSCT.
- Exploring several options to strengthen financing for future developments, including non-dilutive and dilutive sources

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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



Oncology-Focused Platform Fueling a Deep Pipeline of Drug Candidates



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



Groundbreaking Phase 3 Data

Gianfranco Pittari, MD, PhD

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

- → A significant complication following allogeneic hematopoietic stem cell transplantation (Allo-HSCT)
- ightarrow May occur in 50% of patients undergoing Allo-HSCT, presence detected typically within the first 100 days post-transplant



ightarrow Mortality is primarily linked to the involvement of the gastrointestinal tract

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

MaaT013 • aGvHD

→ Salvage → Ouick action



 \rightarrow GvHD is characterized by intestinal dysbiosis which is associated with higher mortality in hemato-oncology²

ightarrow In the Early Access Program (EAP), MaaT013 showed efficacy in aGvHD patients who failed 1 to 6 lines of systemic treatment³

ARES: a Pivotal Phase 3 Trial Exploring MaaT013 in Third-Line aGvHD Following Steroid and ruxolitinib Failure

Milestones: Topline results announced January 8th 2025 | OS expected by end of 2025 | Regulatory submission expected mid-2025





ARES

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MaaT013 • aGvHD

ARES patients: Baseline Characteristics

Patients characteristics at baseline	All patients receiving MaaT013 (n=66)
Median age, years (range)	55.5 (24; 76)
Gender n (%)	Male: 35 (53%) 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%)

🕮 Patients with severe aGvHD

91% are Grade III-IV

*MAGIC : Mount Sinai Acute GVHD International Consortium

100% are ruxolitinib refactory

January 2025

ARES: Strong Response to MaaT013 in aGvHD following Steroid and ruxolitinib Failure

MaaT013 • aGvHD
 ODD EMA/FDA

Quick action



ARES: Unprecedented Probability of Survival Compared to Historical Data with Best Available Therapy (BAT)

MaaT013 • aGvHD

Ouick action



MaaT013 demonstrates response-driven prolonged survival, far exceeding expected outcomes in thirdline 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

MaaT013 • aGvHD

Quick action



Communicated Phase 3 topline results (62%) in Refractory aGvHD confirm EAP signals (59%)



An Expert's Perspective



Pr. Mohamad Mohty, MD

Sorbonne University and Head of the Clinical Hematology and Cellular Department, Saint-Antoine Hospital (AP-HP), Paris, France



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: 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

Clear Regulatory Path for MaaT013 in Third Line Refractory aGvHD

- Eligibility of MaaT013 for the centralized procedure confirmed by EMA (Medicinal product status) and rapporteurs and co-rapporteurs appointed
- Target filing of the EMA Marketing Authorization
 Application for MaaT013 mid-2025 (6mths in advance vs previous plan)
- Submission based on validated primary endpoint (28 days GI-ORR) complemented with data on 1y-OS
- Target H2 2026 for European marketing authorization, commence commercialization end of 2026

• **Open IND:** Ongoing dialogue with the FDA to expedite MaaT013 clinical development plan

In the U.S.

- Dedicated and optimized study for the US leveraging
 ARES Phase 3 results
- Continue to support the ongoing Expanded Access
 Program to allow US patients early access to MaaT013
- Targeting potential launch of U.S. Phase 3 study in
 2025, subject to securing funding



→ Ouick action

MaaT013 Addressable Market and Revenues



Potential peak sales of €250m+ worldwide with potential upside from 2L positioning (+1,400 patients)

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 MaaT013
- 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





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

O AII MET

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





→ cGMP

Leading microbiome therapies fully integrated manufacturing and development platform:

streamlined product development, scaleup and GMP process.



Option to expand manufacturing facilities to double capabilities.



Consistent yield (<10% variation)

Campaign #1 Campaign #2 Campaign #3 Manufacturing yield based on FDA/EMA authorized processes



Currently used at 10% capacity **Scalable up to commercial capacity**



Partnership with







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Opportunities to fund the Company's development

Cash position of €27m as of September 30,2024

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Current cash runway into Q2 2025

Exploring several opportunities to fund the Company's developments over the next coming years, **including dilutive and non-dilutive options**





Closing remarks







Thank you

