Press release

Lyon, France – October 4, 2021 – 7.30 AM CET

MaaT Pharma announces the approval of its Registration Document by the French Financial Markets Authority (Autorité des marchés financiers) as part of its proposed IPO on the Euronext Paris regulated market

MaaT Pharma S.A. (the « Company»), a French clinical stage biotech and a pioneer in the development of microbiome[1]-based ecosystem therapies dedicated to improving survival outcomes for patients with cancer, announces today the approval of its Registration Document by the French Financial Markets Authority (*Autorité des marchés financiers*- ***AMF***) under number I.21-057 on October 1, 2021 (the "**Registration Document**").

The approval of this Registration Document is the first step in MaaT Pharma's proposed IPO on the Euronext Paris regulated market (the "**Initial Public Offering**"), subject to market conditions and the approval by the AMF of the Prospectus relating to the operation.

The Company's existing shareholders expressed their intention to support the envisaged transaction by providing pre-commitments ahead of the launch of the IPO. These existing shareholders include Seventure Partners, Health for Life Capital, SymBiosis, Biocodex, Bpifrance, through PSIM fund and Crédit Mutuel Innovation.

Hervé Affagard, Co-founder and CEO of MaaT Pharma, said:

"MaaT Pharma aims to change the global pharmaceutical industry by developing next-generation drugs based on complete microbiome ecosystems. While 25% of the world's population suffers from an altered gut microbiota, our clinical data show that its restoration could play a major role in improving the survival outcomes for patients with acute graft-versus-host disease (following a bone marrow transplant) as well as for patients fighting other liquid and solid tumors. Our proposed IPO comes at a pivotal time in our history, as first key development milestones have been achieved, with promising Phase 2 clinical results and the launch of a Phase 3 trial planned before year end. Based on these advances, our proprietary AI-powered and omics-based technologies, the expertise of our team and our high-precision biomanufacturing capabilities, we can now leverage these decisive advantages to pursue our growth trajectory. We expect first important milestones in the second half of 2022. We also benefit from the financial support of widely recognized international investors, who have already invested around €37 million to date, and from government bodies. We hope to address major current and future public health issues for the benefit of millions of patients."

[1] The gut microbiome is constituted by all the microbes (bacteria, archaea, yeasts, viruses, ...) naturally present in the gut. It plays an important role in the education and the modulation of the immune system and the metabolism.

An innovative therapeutic approach based on microbiome modulation to improve survival in patients with liquid and solid tumors

The gut microbiota is an assembly of rich and diverse microorganisms ("ecosystem") and contributes to maintain a symbiosis[2] between the host and the billions of naturally present microbes in the human body. This symbiosis is essential for human health and regulates our immune homeostasis, as 80% of immune cells reside in the intestine[3], and our metabolism. A balanced symbiosis generates protection through a stronger intestinal barrier and contributes to the education and maturation of the immune system against potential pathogens. However, lifestyle, diet, or the use of toxic drugs for the microbiome can alter this symbiosis. This alteration is referred as “dysbiosis” and is notably illustrated by a loss of diversity of microorganisms. This condition represents a danger for the host because bacteria could induce deleterious, inflammatory reactions or make anti-cancer treatments less effective.

To address major unmet medical needs in oncology, MaaT Pharma is designing a groundbreaking and revolutionary therapeutic approach based on gut microbiome modulation. The company develops high-richness and high-diversity drug candidates derived from healthy donors or produced by co-fermentation, using its MET (Microbiome Ecosystem Therapy) platform.

MaaT Pharma's main drug candidates are:

- **MaaT013** for the treatment of acute graft-versus-host disease (aGvHD), ready to enter **Phase 3 clinical trial** (application submitted); MaaT013 is also expected to enter a Phase 2 proof-of-concept trial to evaluate its impact on response rates to immune checkpoint inhibitors in metastatic melanoma.
- **MaaT033** for the improvement of survival in patients receiving allo-HCT[4] consecutively to acute myeloid leukemia (AML) or other liquid tumors, **currently in a Phase 1b trial**.
- **MaaT03X**, a new class of microbiome-based therapies to be used in combination with immuno-therapy in oncology, targeting solid tumors. MaaT03X is currently in preclinical testing.

MaaT013: lead microbiome therapy candidate entering Phase 3 trial for the treatment of acute Graft-vs-Host Disease (aGvHD)

In hematology-oncology, MaaT Pharma is developing **MaaT013**, the company’s most advanced therapy candidate. MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-from-healthy-donors[5], **high-richness, high-diversity** Microbiome Ecosystem Therapy, containing Butycore™ [6] and presented as an enema[7].

MaaT013 aims to restore healthy microbiome functions in patients fighting leukemia, lymphoma, and myeloma to correct severe gut microbiota alteration due to stressors such as antibiotics and chemotherapies, and thus treat acute Graft-vs-Host disease, a severe and potentially fatal complication following an allogeneic hematopoietic stem cell transplantation (allo-HCT).

MaaT Pharma has gathered positive topline results in a Phase 2 clinical trial in patients with grade III-IV gastro-intestinal predominant aGvHD, as well as positive data from an ongoing Early Access Program taking place in France for patients having failed multiple lines of treatments. The Company **expects to initiate its pivotal Phase 3 clinical trial** in Europe before the year end in this indication, based on and subject to the assumptions defined by the Company in its Registration Document.

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[2] Symbiosis: mutually beneficial relationship
[3] Castro G.A. & Charles J.A., Am. J. Physiol. 265 (Gastrointest. Liver Physiol. 28): G599-G610, 1993.
[4] Allo-HCT: allogeneic hematopoietic stem cell transplant
[5] This technology combines donations from multiple strictly-vetted healthy donors to maximize richness and diversity while standardizing the product.
[6] Butycore™ is a group of 15 different genera known to product short-chain fatty acids with anti-inflammatory properties. MaaT Pharma’s technology enables to preserve these bacteria and standardize their presence in all MaaT013 and MaaT033 products.
[7] Enema: solution for rectal administration

In 2018, MaaT013 was granted **Orphan Drug Designation** by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

MaaT033: drug candidate currently in Phase 1b trial to prevent complications and improve survival after allo-HCT for patients with acute myeloid leukemia (AML) and other hematologic malignancies

MaaT033, the second therapy candidate developed in haemato-oncology, is an **oral formulation** with the same active substance as MaaT013. MaaT033 is designed to restore the full functionality of the gut ecosystem in order to **improve survival and prevent complications following allogeneic-Hematopoietic Stem Cell Transplantation (allo-HCT)** in patients with liquid tumors.

MaaT033 is currently evaluated in a dose-ranging Phase 1b clinical trial in patients with acute myeloid leukaemia (AML) following intensive chemotherapy and presenting severe dysbiosis.

If proof of concept is established with this clinical study, MaaT Pharma plans to position MaaT033 in a pivotal Phase 2/3 clinical trial, scheduled to begin in the second half of 2022. This upcoming trial will evaluate the capacity of MaaT033 to improve survival by preventing complications (notably graft-vs-host-disease and infection occurrence) for all patients undergoing an allo-HCT procedure, regardless of the cancer type.

MaaT03X: a novel class of co-fermented microbiome ecosystem therapy aiming to increase response rate to immune checkpoint inhibitors in multiple solid tumors, with the potential of large-scale production

Immune check-point inhibitors (ICI) have marked a revolution in the treatment of oncological malignancies. Despite this progress, overall response rate to ICIs remains between 20-40% in many addressed indications[8]. Notably, **both the diversity and the composition of the gut microbiota** have been found to increase the response rate to ICIs[9].

Based on this rationale, a **Phase 2, proof of concept, trial is expected to start by the end of 2021** to evaluate the potential of **MaaT013**, a drug candidate designed to maximize gut microbiota's richness and diversity, in improving the response to ICI in patients with metastatic melanoma. This study is sponsored by AP-HP and will be executed with a consortium of leading hospital and research institutions, including Institut Gustave Roussy, which will contribute as a clinical center, and INRAE, which will conduct specific analyses. MaaT Pharma will contribute by supplying MaaT013 and conducting metagenomic analyses.

In the mid-term, MaaT Pharma aims to **develop synthetic products that mimic "ICI-responders" profiles, which will combine richness, diversity, and indication-specific functional bacterial networks**, aiming to improve the overall response rate to ICI. The Company has designed the **MaaT03X** product range, which relies on the one hand, on the design of indication-specific, tailor-made full ecosystem products, by analyzing clinical data with the artificial intelligence **gutPrint®** platform, and on the other hand on a groundbreaking **co-fermentation technology**, which allows to manufacture products at greater scale, in compliance with cGMP requirements. The latter exploits the natural interactions within the ecosystem to improve manufacturing quality and yields and to generate products that leverage all the functional diversity of the gut microbiome. **The first MaaT03X candidate is expected to enter clinical testing in H1 2023**, in combination with ICI, for the treatment of an undisclosed solid tumor with a high unmet medical need.

[8] Source: phase 3 data for Keytruda® and Opdivo® in certain indications
[9] Gopalakrishnan et al., Science 2018 ; Routy et al, Science 2018; Baruch et al, Science 2021, Davar et al, Science 2021

Microbiome Ecosystem Therapy (MET) – A proprietary platform technology to develop and manufacture product candidates at industrial scale

MaaT Pharma has now deployed one of the first global platforms that combines **metagenomic data analysis and proprietary manufacturing processes** to develop and manufacture drug candidates.

This development platform, called MET for Microbiome Ecosystem Therapy, stands on two pillars:

1. **gutPrint®, a proprietary computational biology platform**, structured around state-of-the-art artificial intelligence and machine learning tools, which is the engine at the core of the generation of new drug candidates, based on metagenomic and biologic data collected from patients and healthy donors.

2. **Proprietary resources and processes for cGMP manufacturing**, both for native (donor-derived) products and synthetic (co-fermented) ones, supporting a versatile approach for product development, manufacturing, and industrialization, to ultimately serve hundreds of thousands of patients in multiple potential indications.

A pioneer in the microbiome field aiming to conquer high-value markets

MaaT Pharma targets oncology indications with high unmet medical need, associated with moderate to severe dysbiosis, for which the Company expects gut microbiome modulation could improve outcomes.

Acute Graft-vs-host-Disease (aGvHD) is a severe, potentially fatal disease that is a complication of allogeneic hematopoietic stem cell therapy (allo-HCT). It affects approximately 40-50% of patients receiving an allo-HCT in the 7 major markets (USA, Japan, France, Germany, Spain, Italy, and the UK), which represented approximately **10,000 incident cases in 2020** [10].

Allo-HCT is one of the most efficient ways to improve survival in patients with liquid tumors, such as acute myeloid leukemia. However, this procedure is also a factor of mortality and morbidity in these patients, as it may result in acute graft-vs-host-disease and/or be associated with infections; as such, most fragile patients are often not offered the opportunity to receive an allo-HCT. There were an estimated **22,000 allo-HCT procedures** performed in the 7 major markets in 2018[11].

Immune Checkpoint Inhibitors (ICI) are some of the most used and most efficient cancer treatments, but many patients still fail to respond. The eligible population for ICI treatment in the 4 most prevalent solid cancer types (bladder cancer, non-small-cell-lung-cancer, melanoma, renal cell carcinoma) represents **more than 400,000 patients**[12] every year in the 7 major markets.

An ambitious development strategy

In a market with strong potentials and offering multiple opportunities, MaaT Pharma intends to pursue an ambitious strategy focused on 4 key pillars:

1. **Focus its development on microbiome modulation in oncology** (liquid and solid tumors) in indications with high unmet medical need, to **maximize its expertise and consolidate its pioneer status** in the microbiome field, while preserving its competitive advantage.

2. **Gradually expand its product pipeline by discovering new innovative microbiome-based therapies** in haemato-oncology and immuno-oncology, leveraging its **internal expertise and its proprietary technology platform.** The Company's proprietary technology platform enables to use pre-existing clinical data to significantly accelerate new drug development and reduce associated risks. The combination of gutPrint® with proprietary and exclusive cGMP

[10] Source: Global Data GvHD Epidemiology Report, January 2020
[11] Source: European Society of Blood and Marrow 18 (EBMT)
[12] Source: Global Data Epidemiology reports, 2018-2020

manufacturing processes is used as a cornerstone to strengthen and expand the Company's portfolio.

3. **Build an integrated biopharmaceutical company, which could on the one hand ultimately commercialize its most advanced products**, thanks to the limited number of specialized hospital centers performing allo-HCT and **on the other hand establish potential collaboration agreements** with one or more larger pharmaceutical partners, to develop and/or commercialize new drug candidates generated using its MET platform.
4. **Collaborate closely with regulatory agencies to enable efficient development of a new treatment modality** in this pioneering field. Since 2014, MaaT Pharma has received approval to start multiple clinical trials from the ANSM and other European agencies; MaaT013 also received Orphan Drug Designation from both the FDA and EMA in 2018. Since 2018, the French regulator ANSM has enabled access to MaaT013 in aGvHD through a compassionate use (ex-« ATU nominative ») program.

Availability of the Registration Document

Copies of MaaT Pharma's Registration Document, approved by the AMF on October 1, 2021, under number I.21-057, are available free of charge and on request from the Company, at MaaT Pharma's headquarter 70 avenue Tony Garnier, 69007 Lyon, France, as well as on the websites of the AMF (https://www.amf-france.org) and MaaT Pharma (https://investir.maatpharma.com). The Registration Document contains a detailed description of MaaT Pharma, in particular its business, strategy, financial position, and the corresponding risk factors.

Risk factors

MaaT Pharma draws the public's attention to the risk factors described in Chapter 3 of the Registration Document as approved by AMF on October 1, 2021, under the number I.21-057.

Find all information related to

MaaT Pharma's proposed IPO on:

https://investir.maatpharma.com

Contacts

MaaT Pharma
Hervé AFFAGARD
Co-founder and CEO
+33 (0)4 28 29 14 00
haffagard@maat-pharma.com

MaaT Pharma
Pauline RICHAUD
Corporate Communications Manager
+33 (0)6 07 55 25 36
prichaud@maat-pharma.com

Trophic Communications
Medical & scientific communication
Jacob Verghese or Gretchen Schweitzer
+49 89 23 88 77 31
maat@trophic.eu

ACTIFIN, financial communication
Ghislaine GASPARETTO
+33 (0)6 21 10 49 24
maatpharma@actifin.fr

ACTIFIN, financial media relations
Jennifer JULLIA
+33 (0)6 47 97 54 87
jjullia@actifin.fr

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(ii) in accordance with the other exemptions set out in Article 1(4) of the Prospectus Regulation.

For the purpose of this paragraph, the notion of "offer of Shares to the public" in each of the Member States is defined as any communication in any form and by any means to persons providing sufficient information on the terms of the offer and on the Shares to be offered so as to enable an investor to decide to purchase or subscribe for such Shares.

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