MaaT Pharma Announces the Initiation of a Phase 2a Investigator-Sponsored Clinical Trial Evaluating MaaT013 in Combination with Immune Checkpoint Inhibitors for Patients with Melanoma

Lyon, France, April 7, 2022, 6:00pm CET – MaaT Pharma (EURONEXT: MAAT – the "Company"), a French clinical-stage biotech and a pioneer in the development of microbiome-based ecosystem therapies dedicated to improving survival outcomes for patients with cancer, announced today the initiation of a Phase 2a clinical trial[1] sponsored by AP-HP[2], evaluating MaaT013, MaaT Pharma's lead Microbiome Ecosystem Therapy candidate, in combination with immune checkpoint inhibitors (ICI), ipilimumab (Yervoy®) and nivolumab (Opdivo®), which are standard first line treatments for patients with metastatic melanoma.

The Phase 2a clinical trial is coordinated by Professor Franck Carbonnel, MD, Professor of Gastroenterology at the Kremlin-Bicêtre Hospital in Villejuif, France, and is being carried out in collaboration with INRAE[3] and Institut Gustave Roussy. The trial is a randomized, placebo-controlled study and is expected to enroll 60 patients in France. The primary endpoint is safety, while the secondary endpoint will evaluate MaaT013's potential to improve the response to ICI therapies, as a consequence of MaaT013's impact on the patient's gut microbiome. Patients will be randomized to receive either MaaT013 in combination with both ICIs or a placebo with both ICIs. MaaT Pharma will provide MaaT013 drug candidate and the placebo for this study as well as perform the microbiome profiling of patients using its proprietary gutPrint® platform. This clinical trial is registered on clinicaltrials.gov.

Several studies have suggested that gut microbiota diversity and richness are predictors of response to ICI treatment[4] in patients with solid tumors. Notably, in two recent studies conducted in melanoma patients[5], fecal microbiota transfer from ICI therapy responders could overcome resistance to that same therapy in non-responders.

[1] NCT04988841: **P**rospective random**I**zed clinical trial assessing the tolerance and clinical benefit of fe**CA**l tran**S**plantation in patient**S** with melan**O**ma treated with CTLA-4 and PD1 inhibitors.
[2] AP-HP: Assistance Publique - Hôpitaux de Paris
[3] INRAE: Institut national de recherche pour l'agriculture, l'alimentation et l'environnement
[4] Routy B. et al, Science 2018, Matson et al, Science 2018, Gopalakrishnan V. et al, Science, 2018
[5] Davar D. et al, Science, 2021 ; Baruch E.N. et al, Science, 2021

About MaaT013

MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, Microbiome Ecosystem Therapy. It is characterized by a consistently high diversity and richness of microbial species and the presence of Butycore™ (group of bacterial species known to produce anti-inflammatory metabolites). MaaT013 aims to restore the symbiotic relationship between the patient's functional gut microbiome and their immune system to correct the responsiveness and tolerance of immune functions and thus reduce steroid-resistant, gastrointestinal-predominant aGvHD. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for acute Graft-versus-Host Disease (aGvHD) and is currently being evaluated in a Phase 3 clinical trial. MaaT Pharma has obtained positive safety and efficiency clinical data for 76 patients with aGvHD (Phase 2 clinical trial and Early Access Program in France).

About MaaT Pharma

MaaT Pharma, a clinical stage biotechnology company, has established a complete approach to restoring patient-microbiome symbiosis in oncology. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has launched, in March 2022, a Phase 3 clinical trial for patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, supports the development and expansion of its pipeline by determining novel disease targets, evaluating drug candidates, and identifying biomarkers for microbiome-related conditions.

The company's Microbiome Ecosystem Therapies are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome, in liquid and oral formulations. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to support the integration of the use of microbiome therapies in clinical practice.

MaaT Pharma is listed on Euronext Paris (ticker: MAAT).

Forward-looking Statements

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements.

Contacts

MaaT Pharma – Investor Relations
Hervé AFFAGARD
Co-Founder and CEO
Siân Crouzet, COO/ CFO
+33 4 28 29 14 00
invest@maat-pharma.com

MaaT Pharma – Media Relations
Pauline RICHAUD
Senior PR & Corporate Communications Manager
+33 6 07 55 25 36
prichaud@maat-pharma.com

Trophic Communications
Corporate Communications
Jacob VERGHESE or
Gretchen SCHWEITZER
+49 89 23 88 77 31
maat@trophic.eu