



MaaT Pharma Announces Update on U.S. FDA Investigational New Drug Application for MaaT013 in Patients with Acute Graft-versus-Host Disease

Lyon, France, August 10th, 2022, 6:00 pm CET – [MaaT Pharma \(EURONEXT: MAAT – the “Company”\)](#), a French clinical-stage biotech and a pioneer in the development of Microbiome Ecosystem Therapies™ (MET) dedicated to improving survival outcomes for patients with cancer, today announced that it received a communication from the U.S. Food and Drug Administration (“FDA” or “the Agency”) related to the Company’s Investigational New Drug (IND) application filed in June 2021 to initiate in the U.S. an open-label, single-arm Phase 3 clinical trial of the Company’s drug candidate, MaaT013, in patients with steroid-resistant acute Graft-versus-Host Disease (aGvHD). Following questions raised by the FDA in August 2021 on this application in a clinical hold letter, the Company had previously submitted a request for a Type A meeting, as well as detailed responses to the Agency’s questions.

A response letter was received in the evening on August 8th, 2022, Central European Time (CET). It indicates that the Agency maintains the clinical hold on MaaT013 in the U.S. and details the FDA’s position on the clinical trial. The Agency acknowledged that it received satisfactory answers from the Company on multiple clinical and manufacturing-related questions that the Agency had initially raised. However, the Agency requires additional information, notably regarding the safety and efficacy of the Company’s “pooling” approach (*i.e.* mixing donations from multiple donors to achieve higher richness, diversity and better standardization of the product). The Company is also evaluating additional recommendations made by the Agency regarding the trial design.

“We value the FDA’s continued engagement as we seek to extend the Phase 3 clinical trial of MaaT013 to the U.S. and we intend to work with the Agency to resolve the issues raised in the communication, while implementing a defined strategic plan to continue to deliver on our key milestones,” said **Hervé Affagard, CEO and co-founder of MaaT Pharma**. *“To date, data gathered from more than 120 patients with aGvHD who received MaaT013 in Europe as part of our early access program in France and our completed Phase 2 trial in Europe, indicated a positive safety and efficacy profile for MaaT013. We remain focused on bringing innovative and safe microbiome therapies to patients with refractory aGvHD.”*

MaaT Pharma is now in the process of preparing the next steps in the interaction with the FDA, potentially including a Type A meeting dedicated to discussing the remaining questions. In parallel and in line with its goal to reach patients globally, the Company will continue the

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development of MaaT013 in Europe and expand European recruitment for its [ongoing Phase 3 trial](#) evaluating MaaT013 in 75 patients. There are currently 19 active clinical sites in France, Germany, and Spain and the Company has submitted clinical trial applications in three additional European countries. The overall expected timelines for the Phase 3 trial and, if approved, commercialization of MaaT013 in Europe remain unchanged.

In parallel, the Company continues to prepare for the initiation of a Phase 2/3 trial in Europe to evaluate its second native (donor-derived) asset, MaaT033, in patients with blood cancers receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT). This clinical study is expected to start in Q4 2022.

The Company also continues to prepare a first-in-human trial of its first co-fermented MaaT03X candidate in both Europe and the U.S. This new class of drug candidates aims to improve the anti-cancer efficacy of immune checkpoint inhibitors in patients with a yet undisclosed solid tumor having a high unmet need.

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 in Europe, 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 the first company developing microbiome-based therapies 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.

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