MaaT Pharma Receives U.S. FDA Response Outlining Path Forward for Investigational New Drug Application for MaaT013 in Patients with Acute Graft-versus-Host Disease and Reports Cash and Revenues for Fourth Quarter 2022

Lyon, France, February 3, 2023, 7:30 am 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 reported that the U.S. Food and Drug Administration (FDA or the "**Agency**") has responded to the Company's Investigational New Drug (IND) Application to initiate in the U.S. an open-label, single arm Phase 3 pivotal clinical trial evaluating the safety and efficacy of MaaT013 in patients with steroid-resistant acute Graft-versus-Host Disease (aGvHD). The FDA letter indicates that the Agency agrees to a defined list of conditions that could enable clinical evaluation of MaaT013 in the U.S. These measures will be included, by the Company, in the IND filing. The communication therefore provides a path forward regarding MaaT Pharma's "pooling" technology for this IND. The Company will promptly prepare a complete response letter and in the interim, the clinical hold remains.

"We appreciate the FDA's continued commitment and are satisfied that the Agency has provided a clear and, we believe, achievable roadmap for the MaaT013 IND," **said Hervé Affagard, CEO and co-founder of MaaT Pharma**. *"The dialogue with the FDA remains constructive and positive as it lays the groundwork for the clinical evaluation of our pipeline in the U.S. We are confident about implementing the next steps and we will update investors in due course."*

As announced in August 2022, the FDA had requested further clinical and manufacturing-related information including data on the safety and efficacy of the Company's "pooling" technology approach (i.e., mixing donations from multiple donors to achieve higher richness, diversity, and better standardization of the product). The Company submitted to the FDA detailed responses to these requests as announced in the press release dated January 24, 2023. In parallel, and as a reminder, the Company continues the development of MaaT013 in Europe with its ongoing international multicenter open-label, single arm, pivotal Phase 3 trial "ARES" evaluating MaaT013, which is progressing as planned. A review by an independent data safety and monitoring board (DSMB), is expected in the first half of 2023 after enrollment of half of the patients in the study.

Separately from the information above, MaaT Pharma reported its cash position as of December 31, 2022, and its revenues for the fourth quarter of 2022.

Cash position[1]

As of December 31, 2022, total cash and cash equivalents were EUR 35.2 million, as compared to EUR 40.3 million as of September 30, 2022 and EUR 43.3 million as of December 31, 2021. The net decrease in cash over the fourth quarter 2022 was EUR 5.1 million reflecting financing of operations and the ongoing development programs fully in line with the plans. As announced in a press release on January 24, 2023, the Company has extended its cash runway to end of Q4 2023, as compared to end of Q3 2023 as previously announced.

Revenues in Q4 2022[1]

MaaT Pharma reported gross revenues of EUR 0.6 million for the quarter ended December 31, 2022, compared with EUR 0.4 million for the same period of 2021. Full year gross revenues for 2022 amount to EUR 1.4 million compared to EUR 1.0 million in 2021. Revenues correspond to compensation invoiced in relation to the compassionate access program, as approved by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM).

About MaaT013

MaaT013 is a standardized, high-richness, high-diversity Microbiome Ecosystem TherapyTM containing ButycoreTM (group of bacterial genera known to produce immuno-regulatory metabolites). It 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 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). MaaT013 is an off-the-shelf, healthy-multi-donors-derived product intended for acute, hospital use.

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, an open-label, single arm Phase 3 clinical trial in 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

[1] Unaudited data

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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