MaaT Pharma Announces U.S. FDA Lifts Clinical Hold on Phase 3 Investigational New Drug Application for MaaT013 in Patients with Acute Graft-versus-Host Disease

Lyon, France, April 24, 2023, 7:30 am CET – MaaT Pharma (EURONEXT: MAAT – the "Company"), a clinical-stage biotechnology company and a leader 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 lifted the clinical hold and cleared the 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 to treat gastrointestinal acute Graft-versus-Host Disease (aGvHD) as a third line of treatment.

"We are grateful for the FDA's continued engagement and are very pleased with the lift of the hold on MaaT013's IND application. This is the first time the Agency has authorized the Phase 3 clinical evaluation in the U.S of a microbiota-based live biotherapeutic based on a pooling technology[1], which provides greater bacterial diversity, in a standardized and scalable approach, with the goal of safely improving patients' outcomes. This major milestone is fundamental to the strategic decisions regarding the development of our portfolio outside Europe and to the Company's outlook in the U.S.," **said Hervé Affagard, CEO and co-founder of MaaT Pharma**. *"The U.S. represents an important market for our therapeutics, and we have already benefited from our previous discussions with the FDA by adapting our pooling technology for our entire pipeline according to the guidelines received during this regulatory process."*

In parallel to the resolution of the clinical hold with the FDA, the development of MaaT013 has significantly progressed in the ongoing international multicenter open-label, single arm, pivotal Phase 3 trial (ARES) launched in March 2022 in Europe, along with the ongoing accumulation of encouraging data from the Early Access Program. In this context, before initiating clinical activities in the U.S., MaaT Pharma intends to consult with the FDA on the next steps of the regulatory process to bring MaaT013 to US patients in the most expeditious

[1] *Pooling technology: this technology, central to MaaT Pharma's MET platform, is referred to as pooling because it involves the procedure and process of combining multiple donor samples.*

way possible while the Company continues the late-stage clinical development of MaaT013 in Europe.

"Today's positive answer is also an exciting moment for MaaT Pharma in its mission to help patients through safe and innovative medicines. It also confirms the robustness of our protocols for donor screening and selection which are now authorized for clinical evaluation in the U.S. as well as in Europe. We are now in a position to start discussions with the FDA for the clinical evaluation of MaaT033, our second drug-candidate, in the U.S.," **added Mr. Affagard.** *"This step forward for us will also contribute to progress across the microbiome field and confirms MaaT Pharma's position as a leader in the industry."*

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 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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