



MaaT Pharma Announces European Medicines Agency Granted MaaT033 Orphan Drug Designation aiming to improve overall survival in patients undergoing Hematopoietic Stem Cell transplantation

- MaaT033 (capsule), which is being developed as an adjunctive and maintenance therapy to improve overall survival in allo-HSCT, has received orphan drug designation (ODD) status from the European Medicines Agency (EMA).
- ODD is reserved for medicines treating rare, life-threatening, or chronically debilitating diseases. The status offers key benefits including market exclusivity, clinical protocol assistance, waivers or reductions in regulatory fees.

Lyon, France, September 7, 2023, 7:30am 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, announced that the European Medicines Agency (EMA) has granted MaaT033 orphan drug designation aiming to improve overall survival in patients undergoing HSCT and has recognized the significant benefit that MaaT033 could therefore bring to this patient’s population. This is the first ODD granted for MaaT033 and the third to date for the Company, which has already obtained ODD status for MaaT013 in the US and Europe.

“The EMA’s decision to grant orphan drug designation to MaaT033, our second clinical-stage asset and first-in-class therapeutics, recognizes the need for new treatment options for patients with liquid tumors and highlights the potential of microbiome-based drugs further strengthening the value of our clinical assets,” stated Philippe Moyen, COO of MaaT Pharma. “We look forward to continuing to collaborate closely with the regulatory agencies to accelerate the development of safe and innovative microbiome therapies.”

About MaaT033

MaaT033, a donor-derived, high-richness, high-diversity oral Microbiome Ecosystem Therapy™ containing anti-inflammatory Butycore™ species, is currently being developed as an adjunctive therapy to improve overall survival in patients receiving HSCT and other cellular therapies. It aims to ensure optimal microbiota function and to address a larger patient population in a chronic setting. MaaT033 has been granted Orphan Drug Designation by the European Medicines Agency (EMA).

About Allogeneic hematopoietic stem cell transplantation (allo-HSCT)

Allogeneic hematopoietic stem cell transplantation (allo-HSCT) for liquid tumors can replace cancerous cells, but the harsh conditioning treatments damage the gut microbiome, which has been linked to decreased survival, increased risk of graft-vs-host disease, and infections due to impaired immune function. Nearly 20,000 allo-HSCT transplantations per year in Europe were reported in 2021 by the European Society for Blood and Marrow Transplantation (EBMT) and continue to increase.

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®, enables the identification of novel disease targets, evaluation of drug candidates, and identification of 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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