



MaaT Pharma Receives Two Clinical Trial Application Authorizations to Evaluate MaaT033 in Two Therapeutic Indications in Europe

- MaaT Pharma received authorizations from French and German regulatory authorities to initiate its Phase 2b clinical trial evaluating MaaT033 in improving survival in patients receiving allogeneic hematopoietic stem-cell transplantation (allo-HSCT)
- MaaT Pharma also received regulatory authorization in France to initiate a Phase 1b pilot study to evaluate MaaT033 in amyotrophic lateral sclerosis (ALS)

Lyon, France, March 27, 2023, 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, announced today that it has received regulatory authorizations for its two clinical trial applications evaluating MaaT033 in hemato-oncology and in amyotrophic lateral sclerosis (ALS). French and German regulatory authorities for drugs and medical products, ANSM (Agence Nationale de Sécurité du Médicament et des Produits de Santé) and BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) respectively, have authorized the application regarding the launch of the Company’s randomized, double-blind, placebo-controlled Phase 2b clinical trial evaluating MaaT033 in improving survival of patients with hematological malignancies receiving allo-HSCT. The Company also received authorization from ANSM, the French regulatory agency, to initiate its Phase 1b pilot study evaluating MaaT033 in slowing down disease progression in ALS. The Company will communicate on inclusion of the first patient in each study, which is expected by mid-2023.

“With the full regulatory authorizations received for conducting both trials in these two significant European markets, we can proceed with the final steps toward enrolling the first patients in each study,” states Hervé Affagard, CEO and co-founder of MaaT Pharma. “The authorizations are an important milestone in our overall strategy to demonstrate the potential of MaaT033 in restoring gut microbiota dysbiosis.”

Phase 2b clinical trial (“PHOEBUS”) evaluating MaaT033 in hemato-oncology

[As previously announced](#), the randomized, double-blind, placebo-controlled Phase 2b clinical trial, called PHOEBUS, will enroll 387 patients, and could include up to 56 sites in Europe. The primary endpoint of the study is to evaluate the efficacy of MaaT033 in improving overall survival at 12 months. Secondary endpoints include the evaluation of safety and tolerability before and after allo-HSCT, and the evaluation of the engraftment of beneficial microbial species from MaaT033.

Phase 1b clinical trial (“IASO”) evaluating MaaT033 in ALS

As previously announced, the Phase 1b pilot study, called IASO, has been developed with experts from the ALS network (FILSLAN and ACT4ALS-MND) and strongly supported by the French patient association (*Tous en Selles contre la SLA*). The trial will enroll up to 15 patients who had their first motor deficit for 6 to 24 months. The key study endpoints are assessment of safety and tolerability of multiple doses of MaaT033. The data readout from the trial is expected for the first half of 2024.

About MaaT033

MaaT033, a donor-derived, standardized, high-richness, high-diversity Microbiome Ecosystem Therapy™ for oral administration is currently being developed as an adjunctive and maintenance therapy to improve overall survival in patients receiving HSCT and other cellular therapies. The capsule formulation facilitates administration in a chronic setting to address a larger patient population while maintaining the high and consistent richness and diversity of microbial species, including anti-inflammatory Butycore™ species.

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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