



Press Release

MaaT Pharma Announces DSMB Approval to Proceed to Cohort 4 out of 5 in Phase 1b CIMON Trial Testing Capsule Formulation of Microbiome Ecosystem Therapy

- Independent Data Safety and Monitoring Board (DSMB) recommends continuing study as planned and initiating dosing of fourth patient cohort
- CIMON clinical trial is evaluating MaaT033, the company's oral capsule formulation of its lead biotherapeutic (MaaT013), in patients with acute myeloid leukemia (AML) following intensive chemotherapy
- MaaT033 is a donor-derived, standardized, high-richness, high-diversity Microbiome Ecosystem Therapy for oral administration

Lyon, France, June 28, 2021 – [MaaT Pharma](#), a clinical-stage biotechnology company focused on developing Microbiome Ecosystem Therapies in oncology, today announced that the Data Safety and Monitoring Board (DSMB) recommended to proceed to the fourth cohort of the dose-finding Phase 1b CIMON clinical trial, without modifications. The DSMB is an independent committee monitoring the progress of the company's clinical trial and is reviewing safety, tolerability and data quality while the trial is ongoing.

"We are very pleased that the third of five cohorts in this important study with MaaT033 has successfully been completed without any safety signals reported. This is a very meaningful step towards determining the target dose of this oral capsule product candidate, and we expect to initiate a pivotal Phase 3 study next year," commented John Weinberg, MD, Chief Medical Officer at MaaT Pharma.

The CIMON trial ([NCT04150393](#)) is enrolling a total of 27 patients at 6 sites across France. It is an open-label Phase 1b study to investigate the maximum tolerated dose of MaaT033, over 7 or 14 days of therapy, that supports optimal gut microbiome colonization in patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome who have undergone intensive chemotherapy.

The CIMON Phase 1b trial is expected to be completed at the end of 2021.

About MaaT033

MaaT033 is an oral, full-ecosystem, off-the-shelf, standardized, pooled-donor, high-richness microbiome biotherapeutic. It is manufactured at MaaT Pharma's centralized European cGMP production facility. MaaT033 is designed to restore the gut ecosystem to full functionality to improve clinical outcomes as well as to control adverse events related to conventional treatments for liquid tumors. The capsule formulation facilitates administration while maintaining the high and consistent richness and diversity of microbial species, including anti-inflammatory "Butycore" species, which characterize MaaT Pharma's Microbiome Ecosystem Therapies.

About MaaT Pharma

MaaT Pharma, a clinical stage company, has established the most complete approach to restoring patient-microbiome symbiosis to improve survival outcomes in life-threatening diseases. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has already achieved proof of concept in acute myeloid leukemia patients and a Phase 2 clinical trial in acute GvHD is completed. Supporting the development and expansion of our pipeline, we have built a powerful discovery and analysis platform, GutPrint®, to evaluate drug candidates, determine novel disease targets and identify biomarkers for microbiome-related conditions. Our 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 spearhead microbiome treatment integration into clinical practice.

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