MaaT Pharma Announces First Patient Dosed in Phase 2 Clinical Trial of Lead Product MaaT013, a First-in-Class Biotherapeutic to Treat Acute GvHD

Microbiome restoration biological drug product to be tested for safety and overall survival impact in patients with acute Graft-versus-Host-Disease

Lyon, France, October 12, 2018 – MaaT Pharma announced today the dosing of the first patient in a Phase 2 clinical trial of its lead microbiome restoration candidate, MaaT013, in patients with steroid-resistant acute Graft-versus-Host-Disease (SR-aGvHD), the most deadly complication in patients that have undergone allogenic hematopoietic stem cell transplantation, a potentially curative therapy against many hematological diseases. aGvHD is a leading cause of death following an allogeneic stem cell transplant due to the transplanted immune cells attacking the patient's tissues. It results in a very dismal outcome and poor overall survival in patients not responding to first line therapy as there are no second-line treatments available. MaaT013 is differentiated by its high microbial diversity and richness that can restore the patient's functional microbiome with the goal of re-establishing homeostasis.

"The dosing of the first patient in our clinical trial, called HERACLES, marks an important milestone in MaaT Pharma's objective to improve survival outcomes in patients undergoing allogeneic stem cell transplantation," commented Hervé Affagard, Co-founder and CEO of MaaT Pharma. "Our strategy is to demonstrate that re-establishing healthy microbial networks in the gut can restore patient-microbiome symbiosis, which improves the patient's ability to recover and increase their chance of survival."

The clinical trial HERACLES is a prospective multi-center study in four European countries to include patients that have received a first-line standard treatment of corticosteroids following allogeneic hematopoietic stem cell transplantation. The enema formulation MaaT013, developed through the MaaT Microbiome Restoration Biotherapeutic (MMRB) platform, will be administered at Day 2, 9 and 16 of the 28-day treatment period. The primary endpoint of the study is to achieve gastro-intestinal and overall GvHD response by day 28 post-inclusion. Patient follow-up will be done 6 months and 12 months after inclusion. Additional details about this European study can be found on www.clinicaltrials.gov using identifier NCT03359980.

"The diversity and complex interactive networks in the microbial ecosystem within the patient are greatly compromised during the occurrence of severe aGvHD and restoring it has the potential to achieve therapeutic impact on survival," said Professor Mohamad Mohty, MD, PhD, international coordinator of the HERACLES trial, Professor of Hematology at Sorbonne University and Head of the Hematology and Cellular Therapy Department at the Saint Antoine Hospital in Paris. "An accumulating body of evidence is corroborating our approach and we look forward to further validating the concept in this controlled European study."

About MaaT013

MaaT013 is the off-the-shelf, reproducible, enema formulation manufactured using MaaT Pharma's integrated MaaT Microbiome Restoration Biotherapeutic (MMRB) platform. The product has a stability of up to 18 months and is characterized by a high diversity and richness of microbial species derived from pooled healthy donors and manufactured at the company's centralized European cGMP production facility. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and is already being administered in compassionate use.

About MaaT Pharma

MaaT Pharma has established the most complete approach to restoring patient-microbiome symbiosis to improve survival outcomes in life-threatening diseases. Committed to treating blood cancers and graft-versus-host disease, a serious complication of allogeneic stem cell transplantation, MaaT Pharma has already achieved proof of concept in acute myeloid leukemia patients. Supporting the further expansion of our pipeline into larger indications, 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 therapeutics are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to spear-head microbiome treatment integration into clinical practice.

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