MaaT Pharma Announces Positive DSMB Safety Review and Continuation of its Phase II HERACLES Study in Acute GvHD

Independent Data Safety Monitoring Board (DSMB) recommends to continue HERACLES study without modification

Lyon, France, February 5, 2019 – MaaT Pharma announced today that its independent Data and Safety Monitoring Board (DSMB) completed its first safety assessment of the company's ongoing Phase II HERACLES study (NCT03359980) with lead biotherapeutic MaaT013 in steroid-resistant, gastrointestinal-predominant, acute Graft-versus-Host-Disease (SR GI aGvHD) after allogeneic Hematopoietic Stem-Cell Transplantation (allo-HSCT). The DSMB confirmed the absence of safety issues during the trial from initiation until the first safety evaluation milestone of five patients treated. Enrollment is on schedule with sites recruiting in France and Poland. Additional sites in three other European countries are scheduled to begin recruitment in early 2019. MaaT013 is the first full-ecosystem, off-the-shelf biotherapeutic emerging from MaaT Pharma's Microbiome Restoration Biotherapeutic (MMRB) platform and has been granted orphan drug designation by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

"The first DSMB assessment confirms our observations of MaaT013's excellent safety profile up to this point, which is instrumental in these severely ill patients," commented Dr. Ronald Carter, MaaT Pharma's Chief Medical Officer.

"After steroid treatment failure, there are currently no approved second-line therapies for SR GI aGVHD; therefore new treatment paradigms addressing this life-threatening condition without serious adverse events that may further compromise the patient's health and survival are desperately needed," added 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. "aGvHD patients have a greatly compromised microbial ecosystem, which has been shown to impact overall patient survival. The goal of MaaT013 is to restore a functional gut microbiome and re-establish bacteria-host cross-talk and immune system homeostasis, which is a very promising new therapeutic avenue."

The HERACLES study is a multi-center, single-arm, open-label study, enrolling 32 patients to evaluate the safety and efficacy of MaaT Pharma's lead microbiome restoration drug candidate MaaT013 in steroid-resistant aGvHD patients. Acute GvHD is a serious, often fatal syndrome typically involving the gut, skin, and liver. Treatments up to now focused largely on suppressing the immune reaction induced by the donor cells derived from the hematopoietic stem cell graft against the host and have remained clinically unsuccessful in most cases, with mortality rates around 80% after twelve months in steroid-resistant cases. Prior to stem cell transplantation, patients who develop aGvHD have been treated with intensive chemotherapy and antibiotics, which are known to severely impact the gut microbial composition.

"MaaT013 represents a very differentiated approach to improving patient outcomes in aGvHD and we strongly believe, based on our and accumulating external scientific data, that microbiome restoration therapies can have a significant impact in oncological indications," said Hervé Affagard, Co-founder and CEO of MaaT Pharma. "We look forward to further investigating MaaT013 in this European study, while working on expanding the trial into other regions to benefit patients globally."

About MaaT013

MaaT013 is the off-the-shelf, reproducible, enema formulation manufactured using MaaT Pharma's integrated MMRB platform. The product has a stability of up to 18 months and is characterized by a high diversity and consistent 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 the European Medicines Agency (EMA) and is already being administered in compassionate use.

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 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 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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