MaaT Pharma Announces Second Positive DSMB Safety Assessment of Phase II HERACLES Study in Acute GvHD

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

- Patient recruitment in the study continues with additional sites opened in Europe -

Lyon, France, April 09, 2019 – MaaT Pharma announced today that the independent Data and Safety Monitoring Board (DSMB) recommended the continuation, without amendment, of the ongoing Phase II HERACLES study (NCT03359980). The HERACLES trial inverstigates the use of 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 second review assessed the safety of MaaT013 after 10 patients treated, reinforcing the absence of safety issues during the trial as confirmed after the first review. Enrollment of patients in the trial continues as planned with additional sites recently opened in Germany and Italy. As of today a total of 13 patients have been treated in the protocol.

"The high mortality rate of up to 80% after 6 months in gastrointestinal-predominant aGvHD poses a significant unmet medical need and we believe that MaaT013 will improve these patients' outcomes through a differentiated approach of restoring their immune homeostasis," said Hervé Affagard, Co-founder and CEO of MaaT Pharma. "The relevance of the microbiome in hemato-oncological diseases is increasingly recognized by the medical community and our mission is to develop the first, safe microbiome-based product to help patients with no other options. We look forward to communicating the top-line data of this trial later this year."

Seperately, the Company announced the presentation of the detailed protocol information on the HERACLES study in a poster at the 45th Annual Meeting of the European Society for Blood and Marrow Transplantation in Frankfurt, Germany, held from March 24th – 27th, 2019. The full poster can be accessed on the Company website through the following link: https://bit.ly/2V2tbnl

About HERACLES

The HERACLES study is a multi-center, single-arm, open-label study, enrolling 32 patients to evaluate the efficacy and safety of MaaT Pharma's lead microbiome restoration drug candidate MaaT013 in steroid-resistant gut predominant 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. Patients with hematological malignancies receive multiple courses of chemotherapy, antibiotics and ultimately conditioning before HSCT, which are known to severely impact the gut microbial composition.

About MaaT013

MaaT013 is the first full-ecosystem, off-the-shelf, reproducible, enema formulation manufactured using MaaT Pharma's integrated Microbiome Restoration Biotherapeutic (MMRB) platform. The product has a stability of up to 24 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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