# MaaT Pharma Completes Third Positive DSMB Assessment Setting High Safety Standard for Human Intestinal Microbiome Whole Ecosystem-Based Therapeutics

**- Independent Data Safety Monitoring Board (DSMB) confirms continuation of Phase II HERACLES study in acute GvHD with no safety concerns occurring within the study -**

**Lyon, France, June 24, 2019** – MaaT Pharma announced today the third positive assessment of the company's lead biotherapeutic, MaaT013, in the ongoing Phase II HERACLES study (NCT03359980) by an independent Data and Safety Monitoring Board (DSMB). Following the second review in April with 10 patients, this review confirms the absence of safety issues during the trial after 15 patients treated. MaaT Pharma has developed a rigorous quality control process for the production of its integrated Microbiome Restoration Biotherapeutic (MMRB) platform, which has been accepted by five European agencies and reviewed by the US Food and Drug Administration (FDA). The process ensures that the highest quality of donor-derived intestinal microbiota are present in the Company's biotherapeutics. The Company is investigating the use of MaaT013 in steroid-resistant, gastrointestinal-predominant, acute Graft-versus-Host-Disease (SR GI aGvHD) after allogeneic Hematopoietic Stem-Cell Transplantation (allo-HSCT).

"Re-establishing the whole microbial ecosystem in the gut to treat serious diseases is a promising approach with the potential to become a widely-used therapeutic modality in the near future. Although the field is in an early stage, MaaT Pharma is pioneering efforts to set the highest standards of safety for developing human intestinal microbiome-based therapeutics and is establishing a standardized drug development framework for these products in close association with European regulatory agencies," said Hervé Affagard, Co-founder and CEO of MaaT Pharma. "Our lead product, MaaT013, the first reproducible, full-ecosystem, off-the-shelf, enema formulation, remains on track to show the potential beneficial effects in hemato-oncological patients with GI-predominant GvHD and we look forward to communicating top-line data from the Phase II HERACLES trial later this year."

MaaT Pharma is a funding member, together with three other European microbiome companies, that have established a joint collaborative 'Intestinal Microbiome-based Medicines European Task Group' under the umbrella of the Pharmabiotic Research Institute (PRI) to create a proposal with recommendations for a common European regulatory framework for commercializing treatments based on targeting a patient's microbiome. The consortium was formed in May 2019 to engage with key stakeholders, including regulatory authorities, with the aim of obtaining a universally accepted product classification for human intestinal microbiome whole ecosystem-based therapeutics across the European Union. Over the last 10 years, the microbiome developed into a promising new therapeutic opportunity for the treatment of a range of serious diseases and several high-impact scientific studies have demonstrated that restoring a healthy microbiome can significantly benefit patients. Moving towards clinical proof-of-concept, it is important to abide by very strict clinical protocols and define a rigorous regulatory process for this drug entity as a new drug class. To find out more about the consortium and its goals, click here.

**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 spearhead microbiome treatment integration into clinical practice.

**Contacts**

**For MaaT Pharma**
Hervé Affagard, CEO
Phone: +33 (0)4 2829 1400
haffagard@maat-pharma.com

**Media Requests for MaaT Pharma**
Dr. Stephanie May or Dr. Jacob Verghese
Trophic Communications
Phone: +49 89 23 88 77 30 or +49 171 185 56 82
E-Mail: may@trophic.eu or verghese@trophic.eu