FINAL PRESS RELEASE

MaaT Pharma Announces Positive Topline Results from Phase 2 HERACLES Clinical Trial with Lead Microbiome Ecosystem Therapy MaaT013 in Patients with Acute Graft-versus-Host Disease

- Study meets primary and key secondary objectives with positive impact and favorable overall safety profile in 21 heavily pre-treated and immunocompromised patients with steroid-resistant, gastrointestinal-predominant aGvHD following stem cell transplantation
- Results in line with previously observed data from a larger patient population treated with MaaT013 as part of an early access program
- MaaT013 expected to advance into pivotal Phase 3 program

Lyon, France, March 17, 2021 – MaaT Pharma announced today positive topline results from its Phase 2 clinical trial evaluating lead microbiome ecosystem therapy, MaaT013, in a high-risk patient population with grade III-IV steroid-refractory, gastrointestinal-predominant acute graft-versus-host disease (SR-GI-aGvHD). The study met its primary endpoint of clinical efficacy, demonstrating a combined 33.3% complete response rate (CR) or very good partial response rate (VGPR) at day 28. In addition, the overall response rate (ORR) was 38.1% at day 28 and the best overall response rate (BORR), *i.e.* the number of patients achieving a response at any point up to day 28, was 57.1%. MaaT013 also showed an acceptable safety profile.

Based on the beneficial clinical outcomes and good safety profile observed to date in over 70 patients treated as part of both the HERACLES trial and an early access program[1], MaaT Pharma plans to initiate a pivotal Phase 3 trial in GI-aGvHD with MaaT013.

John Weinberg, MD, Chief Medical Officer at MaaT Pharma commented: "*Acute GvHD is a devastating disease and treatment is often limited to suppressing the patient's immune system. The therapeutic effect of our lead candidate MaaT013, especially in such a high-risk patient population, is very encouraging. It further validates our approach of restoring the microbial ecosystem to normalize the immune response. The HERACLES trial data, as well as the early access program results obtained in a larger and more diverse subpopulation of patients, demonstrate the real-life benefit MaaT013 can provide to these patients. We look forward to sharing additional data from the HERACLES trial in a peer-reviewed format and to generating further clinical evidence to bring MaaT013 to GI-aGvHD patients worldwide.*"

[1] See https://www.maatpharma.com/maat-pharma-presents-positive-updated-results-with-its-lead-microbiome-biotherapeutic-maat013-in-intestinal-acute-gvhd-at-ash-2020-annual-meeting/

The overall safety profile of MaaT013 continued to be good, in the context of heavily pre-treated and immunocompromised patients with steroid-resistant aGvHD, with no increase in infectious disorders observed.

Professor Mohamad Mohty, MD, PhD, international coordinator of the HERACLES trial, Professor of Haematology at Sorbonne University and Head of the Haematology and Cellular Therapy Department at the Saint Antoine Hospital in Paris added: "*Patients that develop acute GvHD face mortality rates of up to 80%, and a compromised microbial ecosystem has been shown to impact survival outcomes. The results from MaaT Pharma's Phase 2 study clearly indicate that the microbiome ecosystem therapy MaaT013 has a beneficial impact on these patients and that the successful engraftment of the gut microbiome and restoration of its naturally-occurring complex interactive networks is a very promising therapeutic approach in aGvHD.*"

MaaT Pharma expects to present full data from this study, including a more detailed analysis on both primary and secondary endpoints, in a peer-reviewed format and at upcoming medical conferences.

About GvHD

Graft-versus-host disease (GvHD) is a condition that can occur after hematopoietic stem cell transplantation (HSCT), a potentially curative therapy for many hematological malignancies. GvHD can affect the skin, gastrointestinal (GI) tract and the liver; the acute form of GvHD (aGvHD) occurs within the first 100 days after HSCT. GI aGvHD develops due to the transplanted immune cells attacking the patient's tissues and results in high patient morbidity and mortality.

About HERACLES

The HERACLES trial (NCT03359980), a multi-center, single-arm, open-label study, analyzed the efficacy and safety of MaaT013 in patients with grade III-IV GI-predominant aGvHD after allogeneic-HSCT who standard failed first-line treatment of high-dose corticosteroids. A total of 24 patients, including 21 in the per-protocol analysis, received at least one, and up to three doses, of MaaT013 and treatment response was evaluated seven days after each administration and on day 28 after the first dose. Patient follow-up was performed at 3 months and 6 months with a final follow-up at 12 months after study inclusion.

About MaaT013

MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, high-richness microbiome biotherapeutic in enema formulation. The product is characterized by a high diversity and consistent richness of microbial species. MaaT013 aims to restore the symbiotic relationship between the patient's functional gut microbiome and their immune system to correct the responsiveness and tolerance of immune functions and thus reduce steroid-resistant, gastrointestinal-predominant aGvHD. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). MaaT013 was investigated in a Phase 2 clinical trial (NCT03359980) and is already being administered in an early access program.

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 has been 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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