Press Release

MaaT Pharma Presents Positive Updated Results with its Lead Microbiome Biotherapeutic MaaT013 in Intestinal Acute GvHD at ASH 2020 Annual Meeting

- Data showed MaaT013 to be safe and effective in 29 heavily pre-treated and immunocompromised gastrointestinal (GI) acute Graft-versus-Host-Disease (aGvHD) patients
- Positive GI aGvHD response at Day 28 was achieved in 59% (17/29) of patients treated with MaaT Pharma's full-ecosystem microbiota restoration biotherapeutic
- 9 patients achieved complete response, with steroid and immunosuppressant treatment being reduced or stopped
- 6-month overall survival rate of 52% and 12-month overall survival rate of 46% support positive impact of microbiome restoration in aGvHD

Lyon, France, December 7, 2020 – MaaT Pharma announced today positive updated clinical results from its lead full-ecosystem microbiome restoration biotherapeutic, MaaT013, at the virtual 62nd American Society of Hematology (ASH) Annual Meeting. The data stems from a compassionate use/expanded access treatment program in France called Autorisation Temporaire d'Utilisation Nominative (ATUn), using MaaT013 to treat patients that developed acute Graft-versus-Host-Disease with GI involvement (GI aGvHD) following allogeneic hematopoietic cell transplantation (allo-HCT) and were refractory to multiple lines of treatments, including corticosteroids. Treatment with MaaT013 was well tolerated and provided encouraging signs of efficacy with a 6-month overall survival of 52%, demonstrating the positive impact microbiome restoration can achieve in heavily pre-treated patients. The results were presented by leading hemato-oncological expert Florent Malard, MD, PhD, Associate Professor of Hematology at Saint-Antoine Hospital and Sorbonne University, in an oral presentation on December 6, 2020 at the virtual 62nd American Society of Hematology (ASH) Annual Meeting.

"Acute GvHD is a devastating disease where the transplant donor's immune cells attack the patient's tissue following allo-HCT and to date these patients have limited treatment options and a very low long-term survival rate when steroid-refractory," said Dr Florent Malard MD, PhD, Associate Professor of Hematology at Saint Antoine Hospital in Paris. "These data are very encouraging and we are continuing to see clinical benefits in the larger cohort of patients treated with MaaT Pharma's microbiome restoration therapeutic. The very good overall response observed represents a promising and important step towards providing an effective treatment option for these patients."

In the presented data update, 29 recipients of allo-HCT that progressed to steroid-dependent or steroid refractory aGvHD (22, classical aGvHD; 2, late-onset aGvHD; 5, aGvHD with overlap syndrome) and had failed 1 to 5 lines (median: 3) of systemic treatments were evaluated after treatment with MaaT013. Each patient received a median of three doses of MaaT013 (range, 1-3) and treatment-based responses were observed seven days after each administration and 28 days after administration of the first dose. Nine patients achieved a complete response (CR), 6 a very good partial response (VGPR), and 2 a partial response (PR) at day 28. All 9 patients with a complete response were still alive at the last follow-up (median FU: 444 days (197-654)), suggesting an extended survival in comparison to historic cohorts. In addition, these patients were able to taper or stop steroids as well as immunosuppressants. Notably, 15 patients were still alive at last follow-up (median FU: 313 days (28-654)) and the 6-month and 12-month overall survival were 52% and 46%, respectively. Overall, the data revealed that restoring the microbiome with a full-ecosystem microbiota restoration biotherapeutic provided a positive impact for a majority of the patients and the safety of MaaT013 was satisfactory for all patients.

"These additional positive data from the compassionate use program further support the potential of MaaT Pharma's products, targeting restoration of a functional gut to treat severe and life-threatening diseases," said John Weinberg, MD, Chief Medical Officer of MaaT Pharma. "Seeing the clinical benefit of MaaT013 together with its continued tolerability profile, we believe that our approach can truly make a difference for aGvHD patients. Additionally, we expect the readout from HERACLES, our fully enrolled Phase 2 trial of MaaT013 in steroid-refractory, GI-predominant aGvHD patients, early next year. This will provide a more complete picture of the potential of our product across clinical settings."

About MaaT013
MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, high-richness microbiome biotherapeutic in enema formulation. The product has a stability of up to 24 months and is characterized by a high diversity and consistent richness of microbial species. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). MaaT013 is currently being investigated in a Phase 2 clinical trial (NCT03359980) to evaluate its safety and efficacy in steroid-refractory, GI aGvHD patients.

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 is ongoing. 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 therapeutics 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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