MaaT Pharma Launches European Clinical Trial in Severe Acute Graft-*versus*-Host Disease for patients receiving allogeneic Hematopoietic Stem Cell Transplantation

- Phase II proof-of-concept clinical trial in 21 centers of MaaT Pharma's lead product, MaaT013, for treatment of patients with corticosteroid-refractory acute Graft-*versus*-Host Disease (GvHD).
- MaaT013 has the potential to be a first in class therapy for acute Graft-*versus*-Host Disease.

(Lyon-France, March 5th, 2018) - MaaT Pharma, a clinical-stage biopharmaceutical company, received authorization from competent authorities to **launch its phase II prospective multicenter clinical trial in France. This clinical trial is planned to be extended rapidly to Germany, Poland and Italy**.

Acute Graft-*versus*-Host Disease (aGvHD) is a major complication of allogeneic hematopoietic stem cell transplantation (HSCT), occurring in about one out of two patients, and consists of an immunologically mediated inflammatory reaction of donor immune effector cells against host cells. **MaaT013** is targeting **aGvHD,** a clinico-pathological syndrome that usually occurs within the first month post HSCT and generally involves three organs: **skin** (>80% of patients with GvHD), **gastrointestinal tract** (50-55%) and **liver** (20%). Any one or any combination of these organs may be affected. More than 60% of aGvHD patients fail to have a durable response following corticosteroid therapy **leading to a one-year death rate of 70-80% in this corticosteroid -refractory population**. **Acute GvHD is considered a rare disease with c. 10 000 cases per year in Europe and in the USA**, yet about 35% to 50% of HSCT recipients will develop aGvHD[1].

MaaT Pharma has created a new generation of drugs using Fecal Microbiota Transfer (FMT) which rebuilds and restores the entire gut ecosystem of patients with life-threatening diseases. After evolving its business model to include the development of allogenic FMT drugs (in addition to autologous products), MaaT Pharma has **developed MaaT013, a high Microbiome diversity enema**. The initial goal of this drug candidate is to treat **acute GvHD through the correction of gut microbiota disturbance allowing restoration of immune tolerance, metabolic balance and the barrier function effect for protection against infections**.

MaaT013 is a pharmaceutical product with a complete microorganism ecosystem. It is characterized by a very high diversity microbiome and can be administered via upper or lower route.

High diversity microbiota was shown as a predictive factor of survival in patients receiving HSCT[2] and in patients with GvHD[3].

"At present, the corticosteroid-refractory aGvHD treatment options consist of off-label immunosuppressive therapies showing very modest success rates. The introduction of MaaT013 is a promising new approach aiming to tackle this complex clinical situation and could prove rapidly to be a critical addition to the treatment arsenal" said **Pr Mohamad Mohty,** Professor of Hematology, head of the Hematology and cellular therapy Department at the Saint-Antoine Hospital, Sorbonne University and international lead coordinator for this trial.

"*Targeting the microbiome in the setting of aGVHD is likely to be a key step for improving overall success of HSCT*" declared **Pr Ernst Holler** from the Department of Internal Medicine 3, University Medical Center, Regensburg, Germany, who has pioneered some of the most important and cutting-edge research in this field.

Hervé Affagard, CEO and co-founder of MaaT Pharma, underlines that *"this is the fifth authorized clinical trial for MaaT Pharma and we are focused on advancing the program from this current phase to the market as quickly and efficiently as possible. The trial will be conducted in 21 centers in Europe and we are very proud to collaborate with key leaders in the field in Europe".*

MaaT Pharma's global strategy focuses on onco-hematology with two lead products; one dedicated to treating gut Microbiota alteration in Acute Myeloid Leukemia (for which phase 1 clinical results will be available mid-2018) and one focusing on aGvHD. MaaT Pharma also has exploratory programs in the area of infectious diseases*, "we are currently in the middle of a new fundraising round to support additional clinical trials on the company's lead products"* added **Hervé Affagard**.

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About MaaT Pharma

Founded at the end of 2014, MaaT Pharma (Microbiota as a Therapy) is a clinical-stage biotech company revolutionizing and shaping a new approach to therapies in order to **treat serious diseases linked to gut microbiota imbalances**. With its breakthrough proprietary platforms (GMP Fecal Microbiome Transfer platform and gΛt Print, its proprietary data science platform), MaaT Pharma is creating FMT-based products and solutions for **patients suffering from severe diseases.** Addressing currently unmet clinical needs, MaaT Pharma's revolutionary and rapid approach plays a considerable part in the evolution of treatment therapies. In the upcoming years, with the on-going support from strategic partners and investors, MaaT Pharma will develop patient-friendly solutions (oral forms) to improve overall survival, reduce infectious episodes, reduce Gastrointestinal complications and hinder Multidrug-resistant Bacteria onset.

For additional information, please visit www.maatpharma.com and follow us on Twitter @MaaT_Pharma.

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