# MaaT Pharma announces CE marking for its globally unique medical device

**Lyon (France), June 15, 2017.** *A few days after signing a strategic partnership for the treatment of intestinal dysbiosis by FMT (Fecal Microbiota Transfer), MaaT Pharma pursues its industrialization process with the CE marking of the first ever stool collection and dilution device.*

## Quality, safety and reproducibility: more than a medical device, a technological breakthrough in the field of FMT

### The necessary standardization of a booming activity requiring challenging safety rules ...

The international protocols established by teams who practice FMT vary according to the indications treated and are intended to minimize the risk of transmission of pathogens.

In France, a report published by the ANSM brought this **therapy into the regulatory framework of the drug and made recommendations on the protocol to follow to restore microbiota balance**

While no medical device dedicated to Fecal Microbiota Transfer exists on the market, MaaT Pharma wishes to **standardize and secure this procedure and, in particular, the stool suspension / dilution phase.**

### *Did you know?*

Knowledge of the intestinal microbiota has progressed considerably to such an extent that a major physiological role is now recognized for the 100 000 billion bacteria. Microorganisms are particularly abundant in the colon. The composition of the microbiota changes over a lifetime and may vary depending on external factors such as antibiotics, certain diets or heavy treatments (chemotherapy, etc.). This ecosystem consists of waste and bacteria, more than 70% of which are not resistant to oxygen. The only solution to restore symbiosis: the TMF, which is currently used in hospital pharmacies without a ready-made or *ad hoc* designed device.

### A CE marking, pillar of the first European FMT platform meeting GMP standards

The stool collection and dilution device marked CE is **the first step in the MaaT Pharma value chain, gΛt RePrint ™, which begins with stool collection and ends with medication delivery.**

It ensures both **the safety of users** when collecting and handling the product (no contact with bacteria), **as well as that of administered patients**. Moreover, it preserves the quality of the microbiota thanks to its air evacuation device and its hermetic preservation, thus protecting the bacteria from oxygen, which is damaging to most of them. Maat Pharma's device is entirely composed of medical grade materials, therefore meeting the standard of drug development.

Its **integrated filtration system facilitates the manufacture of the drug**. The device also offers quality traceability with an optimal apparatus to label and condition the collected stools.

## MaaT Pharma, an extremely fast development

### CE marking achieved within two years and three months

After three months of preclinical validation (February-April 2017), MaaT Pharma announces June 15, 2017 **the conformity of its product with the European Directive 93/42 / EEC relating to medical devices.**

Its development started in March 2015 and was accompanied by the arrival of a project manager in October of the same year. A process which has lasted 14 months, leading to the industrialization of the product between May 2016 and March 2017. **The tests resulted in a patent application published in October 2016.**

### Beyond clinical trials ... new partnerships in perspective

MaaT Pharma's stool collection and dilution device will be used in future **clinical trials in onco-hematology and infectious diseases.**

MaaT Pharma's unique system will be made **available to its partners** (collection centers, clinical investigations, etc.) or used **directly on its platform** for the Transfer of Fecal Microbiota.

> *« This device is essential for MaaT Pharma and all our partners involved in the production of our medication. It will simplify and standardize our clinical trials whilst guaranteeing the quality of the material collected. In addition, it will help to preserve the original material and its 600 bacterial species! It plays an essential part in the development of our European platform for the production of clinical batches. »* states Hervé Affagard, CEO and Co-Founder of MaaT Pharma.

**MaaT Pharma is continuously searching for new partners and encourages them to get in touch with the company through its website for more information.**

## About MaaT Pharma

Founded at the end of 2014, MaaT Pharma (Microbiota as a Therapy) is a microbiome–based pharmaceutical company revolutionizing and shaping a selective approach to therapies in order to treat serious diseases linked to gut microbiota imbalances. MaaT Pharma is currently conducting clinical trials on patients suffering from leukemia, and bone and joint infections, as these harsh treatments provoke dysbiosis. MaaT Pharma's revolutionary and rapid approach plays a considerable part in the evolution of treatment therapies. For additional information, please visit **www.maatpharma.com** or follow us on Twitter **@MaaT_Pharma**.

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