Statement following recently FDA reported event with FMT in USA

We recognize that the FDA has sent out an alert regarding the death of a patient following a fecal microbiota transplant (FMT) whose donor(s) had not been tested for multi-drug resistant organisms and are aware of the following dissemination in major news outlets. This is a grave issue that we take very seriously and our thoughts are with the patient's family.

We must strongly emphasize that all donors for any FMT products must be tested for multi-drug-resistant bacteria as well as for other pathogens and should have been excluded from donating for FMT as per regulatory guidelines. This is a very unfortunate event that demonstrates how critical clear regulatory guidelines and strict quality control rules are for the screening and selection of donors as well as for the entire production process. Microbiota therapies are investigational drug products and need to be handled as such.

At MaaT Pharma we have placed significant focus on ensuring the safety of our drug products and have created a fully controlled process that covers the production from the beginning until the finished product, under good manufacturing process (GMP) conditions. We consistently take appropriate measures to ensure our clinical trials are safe and closely monitor infection-related events as we work both with the regulatory agencies as well as with multidisciplinary experts.

MaaT Pharma's full ecosystem biotherapeutics are currently undergoing clinical testing according to good clinical practice (GCP). Our donors are subject to the strictest safety measures of the industry, rigorously vetted by physicians in a process that includes repeated blood and stool testing and screening for more than 45 pathogens, parasites, viruses, and drug-resistant bacteria such as those implicated in the recent event. Our donor selection process has been approved by the most stringent drug agencies in Europe, which have allowed the use of our biotherapeutic drugs in France, Germany, Italy, and in the UK. As expected, our investigational drugs have not produced a single serious adverse event causally linked to our products in all the patients that have received them. Independent drug safety monitoring boards (DSMB) have repeatedly issued us approval reports, allowing us to continue our clinical trials without amendments.

To increase awareness and initiate an educational discussion we have also created the IMM ETG group [https://www.maatpharma.com/imm-etg-a-new-european-initiative-for-intestinal-microbiome-medicinal/] with key companies in the field to advance the regulatory framework. We remain convinced that leveraging the full microbiome ecosystem to treat serious diseases is a very promising therapeutic approach that will be part of the medical treatment arsenal in the near future. MaaT Pharma will continue setting the highest standards in the industry, offering the benefits of this new medical paradigm as we continue developing products for patients with unmet medical needs.

Dr Carter

Chief Medical Officer of MaaT Pharma