FOR IMMEDIATE RELEASE
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OpenBiome Announces New Direct Testing for SARS-CoV-2 in Fecal Microbiota Transplantation (FMT) Preparations and Release of New Inventory

- **Pending completion of stool-based testing for SARS-CoV-2, OpenBiome will expand investigational FMT availability from emergency use to any scheduled patient**
- **OpenBiome is phasing out production of new treatments. It aims to have inventory to meet demand throughout 2021, as a bridge to FDA-approved therapies**

CAMBRIDGE, Mass. – OpenBiome will expand availability of investigational FMT preparations for all scheduled patients, effective May 3, 2021. All material collected from donors since December 1, 2019 will be qualified using a new direct test for the presence of SARS-CoV-2, the virus that causes COVID-19.

Since July 2020, OpenBiome has only been shipping FMT preparations for emergency use from limited inventory manufactured prior to December 1, 2019. In keeping with guidance from the U.S. Food and Drug Administration (FDA), this new direct test allows OpenBiome to now qualify inventory produced in 2020 for clinical use. It supplements ongoing measures that OpenBiome has performed to surveil donor health.

During 2020, OpenBiome, like many organizations, experienced rising costs and significantly reduced revenues throughout the pandemic. The fixed costs associated with maintaining our manufacturing platform rose, while our ability to produce new treatments, and make them available to patients, was challenged by the need for novel stool-based SARS-CoV-2 screening methods to meet our quality and safety standards and to qualify products for patient use.

In navigating this financial situation, along with the anticipated near-term arrival of FDA-approved alternatives to FMT, we made the difficult decision in November to begin phasing out manufacturing of new FMT treatments and sell equipment and related manufacturing assets. This change is necessary to support operating costs in 2021 and will best position OpenBiome to continue serving patients for whom FMT addresses an unmet medical need, while recognizing the diminished long-term need for investigational FMT after a microbiome-based product gains FDA approval.

OpenBiome's goal for the next year is to continue providing investigational FMT until patients have access to an FDA-approved treatment for recurrent *C. difficile*.

We have manufactured a large supply of FMT treatments that will undergo direct testing for SARS-CoV-2. This new test, which has been implemented with review by the FDA, is part of OpenBiome's recent changes to its donor screening program to mitigate the risk of transmission of infectious agents, including SARS-CoV-2. The test—developed by CosmosID, a provider of bioinformatics software and laboratory services for microbiome R&D and infectious disease applications—allows OpenBiome to make FMT treatments manufactured since December 1, 2019 available for patient use.

Upon completion of SARS-CoV-2 testing, OpenBiome plans to start fulfilling orders for any scheduled patients who are eligible for FMT on May 3, 2021. We will provide email notifications to clinical partners and updates on our website as this policy takes effect.

Since 2013, OpenBiome's nonprofit mission has been to expand safe access to FMT—a crucial but investigational treatment for the thousands of *C. difficile* patients who fail antibiotics each year—and to catalyze research on the human microbiome. OpenBiome has, above all, sought to offer a solution to address this urgent, unmet need until the arrival of FDA-approved alternatives. With announcements this past summer that new drug candidates have delivered positive results in pivotal trials, we anticipate the arrival of FDA-approved microbiome-based treatments in the near future.

In 2021, beyond working to make our extensive existing inventory available for patient use, OpenBiome will be building on our work supporting over 50 clinical trials to translate our growing understanding of the human gut microbiome into advancements for public health.

Frequently Asked Questions

Can patients receive an OpenBiome FMT preparation now?
Until May 3, 2021, OpenBiome will be fulfilling orders for urgent use only. Partner physicians may place an order by sending a completed standard order form as well as an Emergency FMT Order form to info@openbiome.org. More information can be found on our Ordering Emergency Use FMT Preparations webpage.

If you are a patient considering a fecal transplant, we recommend discussing FMT with your physician to determine whether it is the right choice for your treatment. More information on FMT can be found on our Patient Support Webpage. For patients looking for a physician, our Find A Doctor tool can help locate an OpenBiome-partnered clinician in your area.

When will OpenBiome be able to fulfill FMT orders for non-emergency cases?
OpenBiome plans to begin shipping FMT treatments for non-emergency cases on May 3, 2021. Existing clinical partners will receive an email update when this service has resumed, and a notice will be posted on our website at www.openbiome.org.

We will require that physicians requesting an FMT confirm the following criteria:

1. Each FMT preparation is requested for an identified patient who is scheduled or awaiting scheduling to undergo an FMT.

2. Each scheduled patient has an active diagnosis of *C. difficile* infection (CDI) that has failed to respond to at least two courses of standard-of-care antibiotic therapy for mild or moderate CDI OR has severe/fulminant CDI that has failed standard-of-care antibiotic therapy.

Existing clinical partners may request multiple FMT preparations. However, each unit must be for a unique eligible patient who meets the criteria above. Eligibility criteria is based on FDA guidance regarding the use of investigational FMT under enforcement discretion.

How does the stool-based SARS-CoV-2 test work?
The test, which was developed by CosmosID, uses RT-PCR, the same molecular technique used in COVID-19 diagnostic testing such as nasopharyngeal swab testing, to check for the presence of SARS-CoV-2 genetic material in donor stool. CosmosID, a Rockville, MD-based provider of industry-leading bioinformatics software and laboratory services for microbiome R&D and infectious disease applications, is directly testing each stool donation that was processed into FMT preparations.