

METAGEN THERAPEUTICS, INC.

Investigating the safety and efficacy of Antibiotic Fecal Microbiota Transplantation (A-FMT) in patients with advanced-stage Parkinson’s disease for microbiome therapeutics development

246-2 Mizukami, Kakuganji,
Tsuruoka-City, Yamagata
997-0052 Japan
<https://www.metagentx.com>

Founded in 2020
President & CEO: NAKAHARA Taku, Ph.D.
No. of employees: 22
Type of Ownership: Private
Primary stock exchange: N/A

January 2025: Conducting joint research with Juntendo University, a global leader in research and development on microbiome therapeutics and Parkinson’s disease treatment. Venture Valuation (VV) interviewed Dr. NAKAHARA Taku, President & CEO.



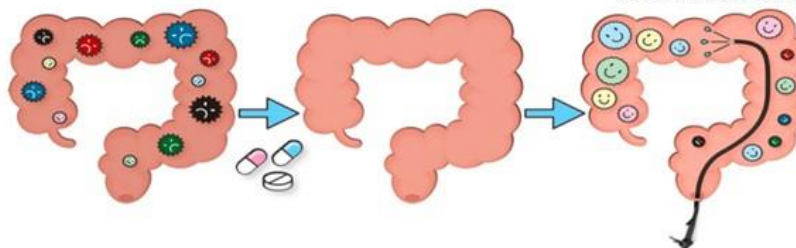
VV: Current research studies indicate a relationship between the pathogenesis of Parkinson’s disease and the intestinal microbiome. There is encouraging evidence that modulating the intestinal microbiome may improve Parkinson’s disease.

Nakahara: The intestinal tract is a habitat where over 40 million bacteria of around 1,000 species are estimated to live together. This is called the intestinal microbiome. Disruption of the intestinal microbiome seems to be involved with various diseases. Parkinson’s disease is one of them.

We have started a randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of A-FMT with 32 patients (40 to 75 years old) in an advanced stage of Parkinson’s disease.

We administer three different antibiotics to the patients to cleanse out their intestines for 5 days, and transplant via colonoscopy 200 mL of intestinal

1. Intestinal microbiota imbalance
2. Cleanse out the intestines with antibiotics
3. Transplantation of healthy intestinal microbiome via endoscope



microbiome solution from a healthy donor to the treatment group, and placebo solution to the placebo group.

The outcome will be analyzed 8 weeks after FMT with the international standard MDS-UPDRS (Movement Disorders Society Unified Parkinson’s Disease Scale) as well as with other measurement methods.¹

VV: You have accumulated experience and data on A-FMT initially proven for treating ulcerative colitis, your leading project. Recently the treatment was accepted to be in the Advanced Medical Care B Program in Japan.

Nakahara: The Advanced Medical Care Program is a fast-track program enabling patients easy access to novel promising healthcare technologies through National Health Insurance coverage. The B Program classifies technologies as more complex to assess than technologies in the A Program.

Our A-FMT method as a medical procedure technology is now being applied to Parkinson’s disease as well as gastrointestinal cancer in combination with immune checkpoint inhibitors. (See below)

As we have identified specific strains as potential drug candidates, our next plan is to provide patients with oral microbiome therapeutics.

| Project Code | Area | Indication | Medical Procedure/ Drug | Basic Research | Preclinical | Exploratory Clinical Study/ Early Phase Clinical Trial (Phase 1/2) | Advanced Medical Care/ Late Stage Clinical Trial (Phase3) | Approval | Partners |
|--------------|------------------------|--|-------------------------|----------------------------------|-------------|--|---|----------|---|
| MGT-001 | Gastrointestinal | Ulcerative colitis | Medical procedure | Advanced Medical Care B Obtained | | | | | Juntendo University |
| MGT-007 | Oncology | Gastrointestinal Cancer (Immune Checkpoints Inhibitor Combination Therapy) | Medical procedure | | | | | | National Cancer Center Juntendo University |
| MGT-008 | Central Nervous System | Parkinson’s Disease | Medical procedure | | | | | | Juntendo University |
| MGT-006 | Gastrointestinal | Ulcerative Colitis | Drug | | | | | | |

VV: You have established J-Kinso Bank, an intestinal microbiome bank, to improve limited supply of feces donations.

Nakahara: Compared to the U.S. and Australia, J-Kinso Bank is still a small scale but is the first intestinal microbiome bank in Japan.

¹ <https://jrct.niph.go.jp/en-latest-detail/jRCTs031240344>

Juntendo University Hospital initiated a feces donation facility led by Dr ISHIKAWA Dai, Associate Professor and our Chief Medical Officer. He has treated 210 patients of ulcerative colitis with 190 donors (as of March 2023)².

In 2025, we are going to start a newly designed facility of J-Kinso Bank near our head office in Tsuruoka City, Yamagata Prefecture and expand in several locations around Japan in close relationship with major medical institutions.

J-Kinso Bank, which supplies rigorously tested and controlled infection risk-free raw materials to medical professionals, plays a vital role in developing microbiome medicine. We are encouraging healthy individuals to support the research and development of microbiome medicine.

VV Comments after the interview:

FMT is the beginning of microbiome medicine innovation. The prospects for a new era of microbiome medicine look encouraging. Two drugs based on FMT have already been approved in the United States: Rebyota in 2022 and Vowst in 2023 to keep recurrent *Clostridioides difficile* infection (a bacterium that causes an infection of the colon) from coming back.

However, as pointed out at the 12th meeting of the Gut Microbiota for Health World Summit in Washing DC in March 2024³, "to continue to advance microbiome-directed treatments, three key themes emerged during the meeting, including (1) better methods to identify actionable targets in the microbiome (2) developing effective strategies to manipulate the microbiome (3) aligning microbiome-based therapies with existing treatment paradigms in the real world."

Contact Mariko Hirano, m.hirano (at) venturevaluation.com

Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, and Medtech), ICT, Femtech, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this "*Let's Interview Series*" with companies with interesting technologies and services. We select and interview thriving companies and organizations especially in Switzerland and Japan.

² DOI: 10.14952/SEI_KAGAKU.2023.950490

³ <https://www.gutmicrobiotaforhealth.com/washington-2024/>