

# APAC DA-EWG

## DA-EWG Session

April, 2025

Jun Terauchi (DA-EWG, JPMA, JMBC)

The 14th Asia Partnership Conference of Pharmaceutical Associations  
DA session

# Accelerating Microbiome-Based Drug Discovery in Asia -The Power of Public-Private Partnerships-

2025.4.22.

Jun Terauchi, Ph. D.

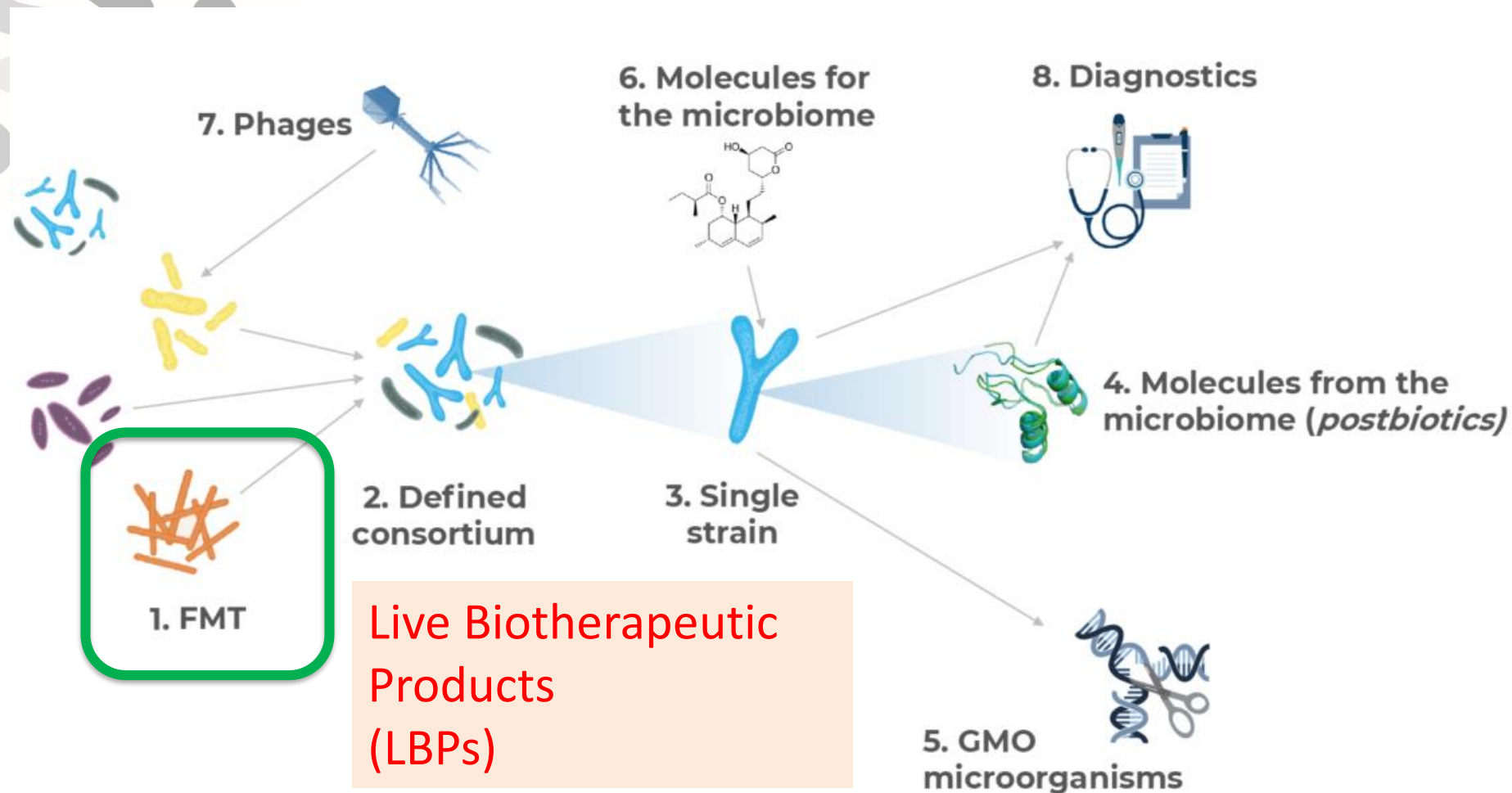
Japan Microbiome Consortium Steering Committee Chair/  
Metagen Therapeutics Inc. CSO



# Today's Contents

1. Recent topics of microbiome Based Drug Discovery and Development
2. Pre-competitive activities by consortiums in the world

# Various Microbiome related drug discovery approach



<https://www.sandwalkbio.com/microbiome-drug-database>

# MBDD(FMT) : Recognized Globally

## Moving towards becoming standard of care



### Stool-derived product development accelerating in the U.S

- ✓ Nov. 2022, world's first FDA approval of REBYOTA for CDI <sup>\*1</sup>



150 mL fecal microbiota suspension containing a consortia of  $10^8$  to  $10^{10}$  (CFU)/mL

- ✓ Apr. 2023, FDA approval of VOWST, as first oral treatment for CDI <sup>\*2</sup>



### Australia leads in FMT regulations globally

- ✓ Nov 2022, BIOMICTRA, a FMT syringe formulation developed by BiomeBank, receives first-ever regulatory approval for CDI <sup>\*3</sup>



### Dec. 2022, European Medicines Quality Directorate sets guidelines for FMT



### Aug. 2022, UK's NICE creates guideline for FMT for CDI

## Regulatory Status

❖ FDA-approved FMT products available in the U.S. and EU

❖ Japan/Asia needs regulatory standards

<sup>\*1</sup>: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product>

<sup>\*2</sup>: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-orally-administered-fecal-microbiota-product-prevention-recurrence-clostridioides>

<sup>\*3</sup>: <https://www.biomebank.com/news/biomebank-announces-world-first-regulatory-approval-for-donor-derived-microbiome-drug/>

# Maat Pharma announced positive outcome of Maat013 for aGVHD



MaaT013 • aGVHD  
ODDEMA/FDA



→ Salvage  
→ Quick action

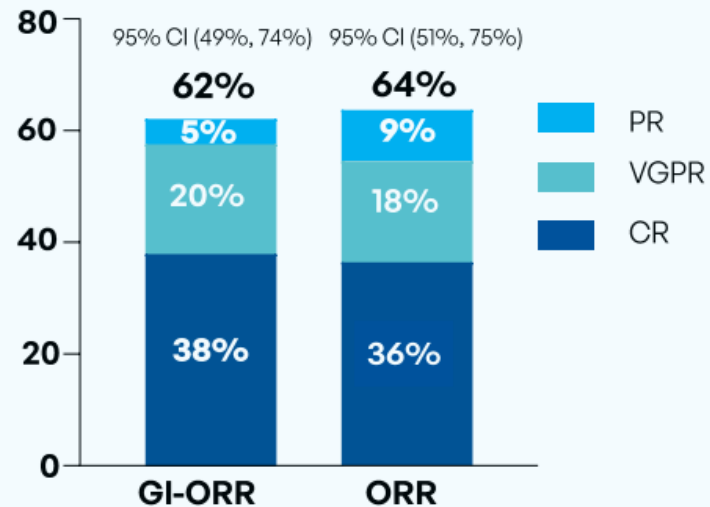
January 2025

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## ARES: Strong Response to MaaT013 in aGvHD Following Steroid and Ruxolitinib Failure

### Topline Results

#### D28 Response Rate (%)



- **62% GI-ORR** with high CR and VGPR rates
- **64% ORR** demonstrating a global systemic response

“These outcomes underscore the curative role of microbiota-based therapies in achieving durable responses leading to prolonged survival. As MaaT013 gains adoption in Europe, it has the potential to redefine care standards for patients facing this life-threatening complication.”

Prof. Malard, MD, hematology professor at Saint-Antoine Hospital and Sorbonne University, lead investigator for the Phase 3 ARES trial



The study met its primary endpoint with a significant gastrointestinal **overall response rate (p < 0.0001)**



# Maat Plans to submit EMA

## MaaT Pharma Announces Positive Outcomes from Final DSMB Meeting for Pivotal Phase 3 Clinical Trial Evaluating MaaT013 in Acute Graft-versus-Host Disease

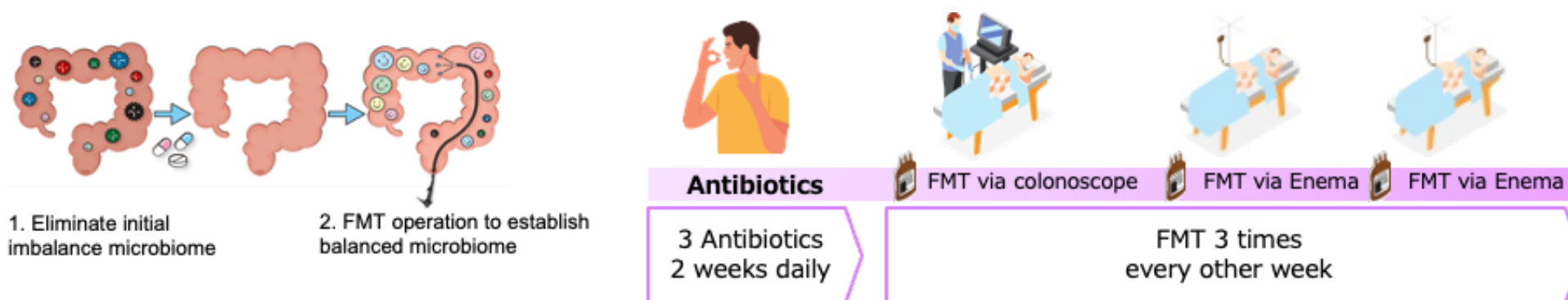
- The Independent Data Safety and Monitoring Board (DSMB) confirmed the remarkable efficacy results and a positive benefit/risk profile of MaaT013 in this patient population
- The Company plans for submission with the European Medicines Agency in June 2025, targeting a potential approval in mid-2026

<https://www.maatpharma.com/march-18-2025-maat-pharma-announces-positive-outcomes-from-final-dsmb-meeting-for-pivotal-phase-3-clinical-trial-evaluating-maat013-in-acute-graft-versus-host-disease/>



# A-FMT for Ulcerative Colitis (UC)

- **Our FMT method: A-FMT (Pretreatment with combination of three Antibiotics and FMT)**
  - Aiming to eliminate the initial imbalance in the microbiome and establish a balanced microbiome through FMT
- **Juntendo University and MGTx initiated pivotal study of A-FMT for UC from Jan. 2023 under the *Advanced Medical Care Program* authorized in Japan**
  - Advanced Medical Care Program offers an official approval path for medical treatments and potential reimbursement
  - We have completed clinical studies with 37 patients in December 2024.







# Indication Expansion



**JMBC**  
一般社団法人日本マイクロバイオームコンソーシアム

## A-FMT clinical study for cancer patients treated with immune checkpoint inhibitors (ICI) in collaboration with National Cancer Center Japan

- Safety study for up to 45 patients with esophageal and gastric cancer will begin soon ( jRCTs031240170, NCCH2308 )
- A-FMT aimed at improving the response rate to ICI



**Antibiotics**

FMT via colonoscope

3 Antibiotics  
1 week daily

FMT

ICI treatment

## A-FMT clinical study for Parkinson's disease is scheduled to begin this year in collaboration with Juntendo University Hospital

- In an aging society, Parkinson's disease continues to increase
- Parkinson's disease has the highest number of patients among designated intractable diseases in Japan



Observational Study

**Medicine**

OPEN

### Fecal microbiota transplantation therapy for Parkinson's disease

A preliminary study

Liu-Jun Xue, MD<sup>1</sup>, Xiao-Zhong Yang, MD, PhD<sup>2</sup>, Qiang Tong, MD<sup>3</sup>, Peng Shen, MD<sup>2</sup>, Shi-Jie Ma, MD<sup>2</sup>, Shang-Nong Wu, MD<sup>2</sup>, Jin-Long Zhang, MD, PhD<sup>4</sup>, Hong-Gang Wang, MD<sup>2</sup>

# Positive clinical outcome in Oncology from Taiwan

 **MICROBIO**

## **MS-20**

### **Innovative Modulator for Immuno-Oncology**

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### What is MS-20?

 **MICROBIO**

- MS-20 is metabolites (without live bacteria) made by commensal anaerobic bacteria.
- MS-20 improves syndrome or treat disease by modulating specific bacteria (increase beneficial ones and/or inhibit pathogens).

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**MS-20 is categorized in the “Microbiome Modulator”.**

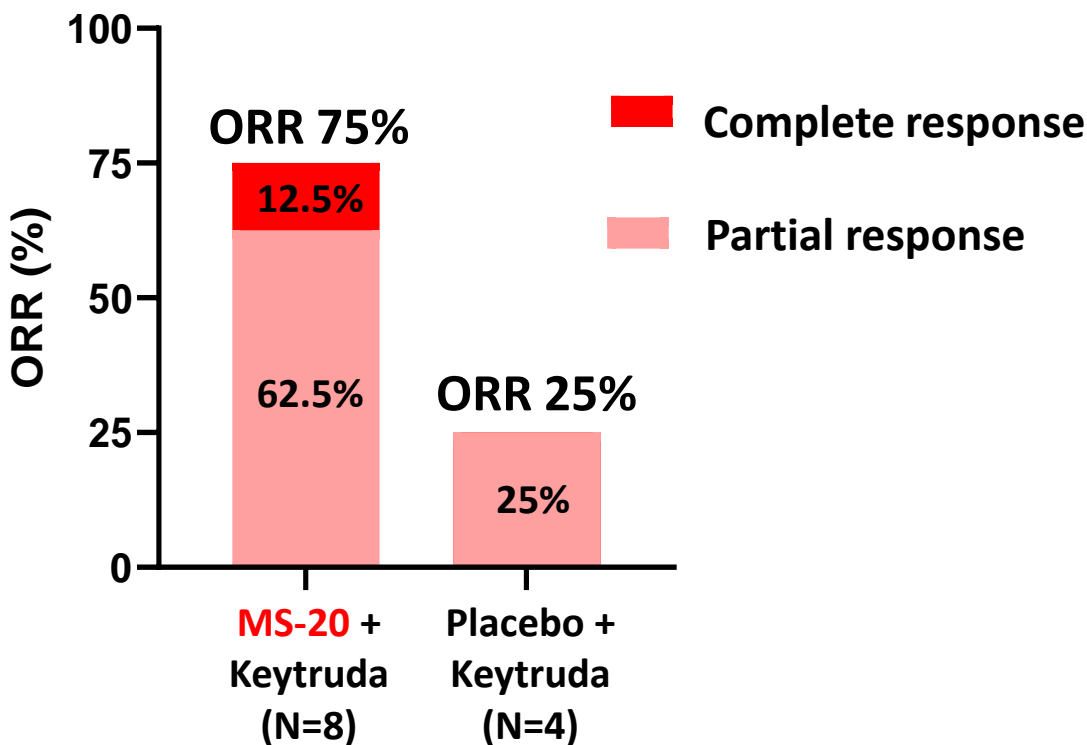


## MS-20 + Keytruda for treatment of advanced NSCLC

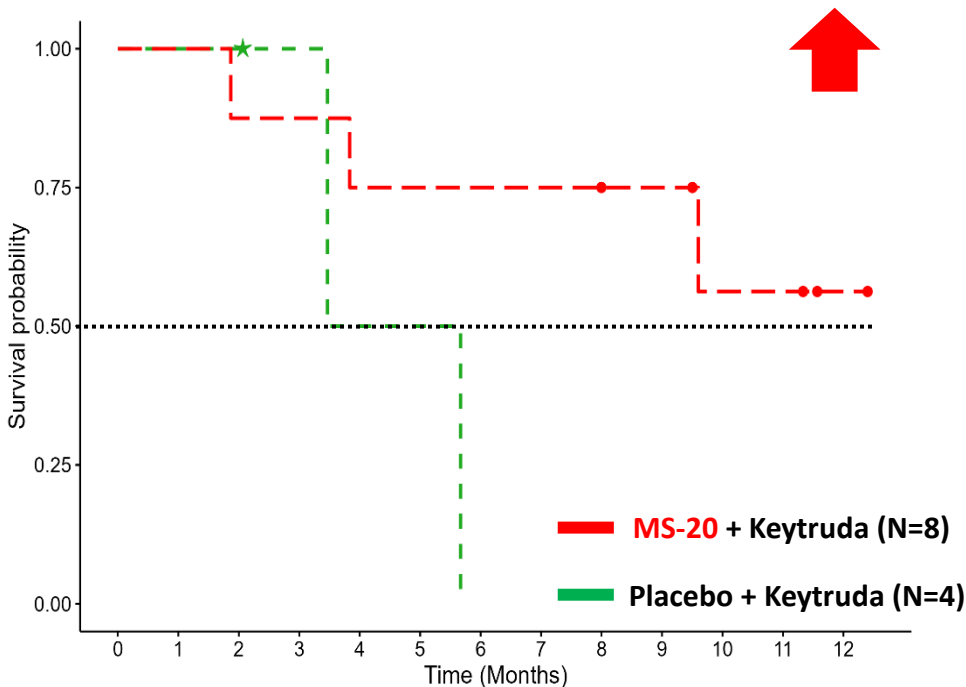
- Placebo + Keytruda, ORR=25%
- MS-20 + Keytruda, ORR=75%, complete response rate=12.5%

- Placebo + Keytruda, mPFS=4.5 months
- MS-20 + Keytruda, in 1 year of observation period, the median PFS has yet to be reached

### Object response rate (ORR)



### Progression free survival (PFS)



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# APMC Public Private Partnership outcome



## Guideline

Development of live biotherapeutic products: a position statement of Asia-Pacific Microbiota Consortium 

 Ching-Hung Tseng <sup>1</sup>,  Sunny Wong <sup>2</sup>,  Jun Yu <sup>3</sup>,  Yeong Yeh Lee <sup>4</sup>, Jun Terauchi <sup>5</sup>, Hsin-Chih Lai <sup>6</sup>, Jiing-Chyuan Luo <sup>7</sup>, Cheng Yen Kao <sup>8</sup>, Sung-Liang Yu <sup>9</sup>,  Jyh-Ming Liou <sup>10</sup>, Deng-Chyang Wu <sup>11</sup>,  Ming-Chih Hou <sup>7, 12</sup>, Ming-Shiang Wu <sup>10</sup>, Jiunn-Jong Wu <sup>13</sup>,  Joseph J Y Sung <sup>2</sup>,  Emad M El-Omar <sup>14</sup>,  Chun-Ying Wu <sup>15, 16, 17</sup>

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<https://gut.bmj.com/content/early/2025/02/26/gutjnl-2024-334501>

Created LBP guideline under **Asia Pacific Microbiota Consortium (APMC)**  
 discussion lead by Taiwan Microbiota Consortium (TMC)  
**Member: Taiwan, Australia, Hong Kong, Japan, Malaysia, Singapore**

# A New US/EU collaboration is started

MTIG(US) and EMIH(EU) Sep. 2024.

The Microbiome Therapeutics Innovation Group (MTIG) today announced an **agreement between MTIG and the European Microbiome Innovation for Health (EMIH) association** for a collaboration to **advance microbiome drug development**, explore synergies between international regulators, and convene cross-continental meetings to incorporate the perspectives of a wide-range of drug developers.

<https://www.globenewswire.com/news-release/2024/09/23/2951313/0/en/European-Microbiome-Innovation-for-Health-and-Microbiome-Therapeutics-Innovation-Group-Announce-New-Collaboration-Agreement.html>

<https://microbiometig.org/statements/>







# A New Initiative in JMBC

- In Japan, JMBC created a new project for the acceleration **of FMT drug development** in January
- JMBC plans to accelerate to develop **FMT drugs with appropriate stakeholders.**
- Preparation of the initiative is on the way.
- In the future JMBC hopes to collaborate with MTIG and EMIH.

# Summary

- Development of Microbiome Based Drug continues to deliver new drugs as one of the **promising new modalities**.
- Industry group such as MTIG, EMIH and JMBC are currently collaborating regulatory authorities, such as FDA, EMA and PMDA to create **appropriate regulatory environment** for Microbiome Based Drugs.
- **Acceleration through Public Private Partnership is powerful way for the new modality drug development.**