

More than cold and cough



CNS (ADEM / MS & Mental Disease

5% - 50% pneumonia and autoimmune diseases can be attributed to Mycoplasma

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Targeting Infection-Triggered Autoimmune Diseases: AI Diagnostics x Preventive Vaccines x Global Trials

Founded in 2005, M Bio Technology is focused on the drug discovery and development

of breakthrough therapeutic strategy for autoimmune diseases caused by infection, proposing vaccine, antibody drug, and AI digital program, based on world-leading platform technology.

Stage: Seed, Pre-Series A, Series A

Industry: Drug Discovery Startup

Number of employees: 5

Market size: \$20 B

Investment opportunity: Seed: \$1M / Pre-Series A: \$3M / Series A: \$10M

Use of funds:

- FDA submission and consulting
- GLP/GMP manufacturing
- Strategic pharma alliances projected to drive \$2B+ enterprise value by 2030.

MANAGEMENT TEAM



Kazuhiro Matsuda, MD, PhD
Founder & CEO
Chairman of Scientific Advisory Boards
Immunology, Microbiology and Internal medicine



Sachie Matsuda, MD, PhD
Founder & CEO
Clinical Development
Dermatologist

CURRENT STATUS

- BDD/BTD application in preparation
- **Efficacy and safety data of non-GLP vaccines have been obtained**
- Collaboration with global multicenter physician-led clinical investigators

CHALLENGE

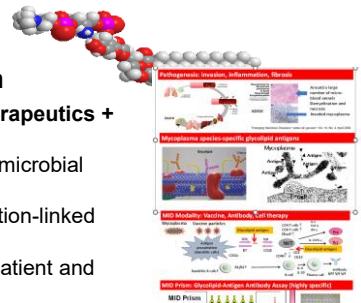
- Autoimmune diseases triggered by infections are often misdiagnosed.
- Current diagnostics fail to detect microbial triggers.
- The essence of the problem was diagnostic method and medical guidelines.

SOLUTION

Mycoplasma glycolipid-antigen

Integrated platform: diagnostics + therapeutics + digital support

1. **MID Prism**— AI diagnostic system for microbial triggers
2. **MID Modality**— Therapeutics for infection-linked autoimmune conditions
3. **MID Navigator** – Digital platform for patient and physician support



MARKET

- Therapeutic: Encephalitis/ADEM/MS – Orphan Disorders
- Preventive: Vaccine strategy interstitial pneumonia

MILESTONES

Clinical Development Timeline (ADEM/MS - Orphan Disorders)		2025	2026	2027	2028	2029	2030	2031
Regulatory consultations (PMDA/DA)	• Targets: MID Prism (AI diagnostic system for microbial triggers), MID Modality (therapeutic for infection-linked autoimmune conditions)	BDD/BTD acquisition • IND submission • Feed-back review, priority • Global trials						
Antibiotic Intervention	• Target naturally infected humans with autoimmune symptoms and AI diagnostic approach for confirmed infection-linked cases	Naturally infected humans • IND submission • IND approval • Antibodies (IgM/IgG) • Immunological profiling • Global multicenter physician-initiated trials	Specific Clinical Research IND					
Therapeutic Vaccine	• Demonstration-based approach for naturally infected patients	Pre-IND safety studies (GLP/GMP) • Vaccine safety studies (GLP/GMP)	Global multicenter physician-initiated trials	Pre-IND	IND	NDA	approval	
Preventive Vaccine	• For high-risk populations (e.g., interstitial pneumonia)	• IND submission • PPs 1/2/3 dose escalation trial • Pre-IND consultation • IND submission • Interstitial pneumonia high risk	Investigator-initiated • Physician Clinical Trials • Corporate Clinical Trials				NDA	approval

REVENUE MODEL

Accelerating Market Access via FDA BDD/BTD Pathways

COMPETITIVE ADVANTAGE

- Unique focus on infection-triggered autoimmunity
- Integrated platform: diagnostics + therapeutics + digital support

EXIT

- Partnering with major pharmaceutical companies accelerates global expansion of preventive vaccines
- Contract lump sum + development, approval, and sales milestones + royalties as return
- Social infrastructure for AI medical infectious diseases