MRM Health's Lead Candidate MH002 Granted Fast Track Designation by U.S. FDA for the Treatment of Mild-to-Moderate Ulcerative Colitis

- Recognizes the potential of MH002 to address a serious medical condition with high unmet need
- Enables accelerated development and increased FDA interactions to streamline review process
- MRM Health will be presenting at upcoming Digestive Disease Week (DDW) 2026, taking place from May 2nd – May 5th in Chicago, IL, USA

Ghent, Belgium – April 30, 2026 – MRM Health, a clinical-stage biopharmaceutical company developing therapeutics for immune-mediated diseases, which unlock the power of the microbiome to restore immune balance, today announced that MH002, the Company's lead rationally designed Live Biotherapeutic Product (LBP) candidate, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of mild-to-moderate ulcerative colitis (UC). MH002 today is the most advanced LBP targeting inflammatory bowel disease (IBD)-specific mechanisms and is composed of a rationally designed microbial consortium of six well-characterized commensal strains.

The FDA's Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important drugs to patients earlier. Fast Track designation enables frequent communication with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval. Products granted Fast Track status may also qualify for Accelerated Approval and Priority Review, and companies may be eligible to submit completed sections of the New Drug Application (NDA) on a rolling basis.

"The FDA's decision to grant Fast Track designation to MH002 recognizes the potential of this promising Live Biotherapeutic Product to address the significant unmet need for innovative and more effective therapies for patients with ulcerative colitis, who have become resistant to standard treatments or for whom conventional therapies have little or no effect," **said Dr. Sam Possemiers, CEO of MRM Health**. "This designation enables us to work closely with the agency to further accelerate the development of MH002 with the goal of getting it to patients in need of well-tolerated therapies with sustained efficacy as quickly as possible."

"Live biotherapeutic approaches are opening entirely new avenues for treating immune-mediated diseases such as ulcerative colitis," **said Professor Geert D'Haens, MD gastroenterologist and investigator at Amsterdam UMC.** "While several treatments are available for UC, this is mostly the case for moderate-to-severe UC patients and many patients still fail to achieve durable remission or require treatment escalation, underscoring the need for novel treatment options. The Fast Track designation for MH002 confirms the growing recognition of microbiome-based therapies as a scientifically grounded strategy to restore gut homeostasis and achieve more durable remission in IBD patients."

Fast Track designation supported by Phase 2a excellent safety and encouraging efficacy signals

The designation was supported by results from a completed Phase 2a clinical trial in mild-to-moderate UC. Over eight weeks of treatment, MH002 demonstrated excellent safety and encouraging efficacy signals, consistent with mucosal healing and anti-inflammatory activity, recovery of microbiome balance, and induction of clinical remission. No safety signals or adverse reactions were observed. MH002 also showed positive outcomes in an open-label study in acute pouchitis, further underscoring its broad therapeutic potential.

MH002 is an orally administered capsule for mild-to-moderate ulcerative colitis and pouchitis, designed to restore microbiome balance and promote mucosal healing and immune rebalancing without immunosuppression. The product candidate will be evaluated in a clinical Phase 2b study (STARFISH-UC;

NCT07296315) in patients with mild-to-moderate UC. The study will enroll approximately 204 patients and includes a 12-week induction phase comparing two MH002 dosing regimens versus placebo, followed by a 40-week open-label extension phase. The trial will be conducted across sites in Europe and the United States, with first results expected in Q4 2027.

Upcoming event:

MRM Health will be presenting at the Digestive Disease Week (DDW) 2026, taking place May 2 – 5, 2026 in Chicago, IL, USA.

Poster Session:

Date & time	Presenter	Title
Tuesday, May 5th 12:30pm – 1:30pm CDT Track: Inflammatory Bowel Diseases	Sam Possemiers, PhD CEO, MRM Health	Tu1533: Studying treatment of mild-to-moderate ulcerative colitis with MH002, an optimized live biotherapeutic product: insights from analyzing first clinical data for the design of a confirmatory trial

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About MRM Health

MRM Health is a clinical-stage biotech developing innovative microbiome-based Live Biotherapeutic Products for chronic inflammatory diseases with high unmet need. Its CORAL® platform enables the design and manufacture of disease-focused microbial consortia with enhanced efficacy and scalability. In addition to advancing lead program MH002 into pivotal clinical development in ulcerative colitis and the orphan disease indication, pouchitis, MRM Health has ongoing preclinical programs in other inflammatory diseases and immune-oncology. In September 2025, MRM Health successfully closed a 55M€ Series B round led by Biocodex, with strong support from ATHOS, BNP Paribas Fortis Private Equity and existing investors SFPIM, AvH, OMX Europe VF, QBic and VIB.

For more information, please follow us on LinkedIn or visit the website at www.mrmhealth.com.

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