PRESS RELEASE

MRM Health Reports Safety and Positive Efficacy Data in Pouchitis in Phase 2a Clinical Study with MH002

- Met primary endpoint of safety: MH002 was safe and well tolerated with no evidence of adverse reactions when administered for 8 weeks.
- Clinical remission rate of 46% at week 8, a mean decrease in the modified Pouchitis Disease Activity Index (mPDAI) symptom score of 42% and a concomitant mucosal healing and reduction of mucosal inflammation.
- Following recent positive results obtained with MH002 in Ulcerative Colitis, consistent treatment effects observed with MH002 in Pouchitis further underscore its potential in indications characterized by mucosal damage and inflammation.
- Initiation of Phase 2/3 development enabled based on recent positive regulatory feedback.
- MH002 is currently the most advanced rationally-designed microbiome consortium therapy in the field of Inflammatory Bowel Disorders (IBD).

GHENT, Belgium, April 16, 2024 – **MRM Health NV, a clinical-stage biopharmaceutical company developing innovative therapeutics for inflammatory, CNS and metabolic diseases, today reports positive topline results from its Phase 2a clinical trial with MH002 in the orphan disease indication Pouchitis.**

MRM Health's MH002-PC-201 study was a multi-center, open-label clinical trial in 14 acute Pouchitis (PC) patients at multiple clinical sites in Belgium and Italy. The study was designed to evaluate safety (primary objective), initial efficacy, and mechanistic effects of MH002 over 8 weeks. More information about the trial is available at clinicaltrialsregister.eu.

The trial met its primary objective with an excellent safety and tolerability at a fixed dose of 400mg per day over 8 weeks' administration. Treatment-Emergent Adverse Events (TEAE) reported were predominantly mild and unrelated, and there was no evidence of adverse reactions related to MH002.

It also demonstrated initial efficacy in clinically relevant parameters, including a 46% clinical remission rate after 8 weeks of treatment (based on the definition used Travis et al., NEJM 2023 and using investigators' assessments), and a decrease in modified Pouchitis Disease Activity Index (mPDAI) cumulative symptoms score of 42%. Clinical remission coincided with improvement of fecal urgency, normalization of stool frequency, mucosal healing (mPDAI endoscopic score, PDAI histology score and reduced ulceration) and reduction of mucosal inflammation (fecal calprotectin).

"*These new clinical results further enhance the positive clinical data previously reported with MH002 in the treatment of Ulcerative Colitis (UC), indicating that MH002 was safe and well tolerated by patients with active gut inflammation and that it demonstrates potential efficacy in acute Pouchitis,*" **commented Séverine Vermeire, coordinating investigator of study MH002-UC-201 and Professor of Medicine at the KU Leuven, Belgium.** *"For both Pouchitis and UC there is a significant unmet medical need for treatments modulating the gut microbiome, and I look forward to MH002 progressing to late-stage clinical development in view of making it available to patients as soon as possible."*

Bruce Sands, Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York, and paid consultant to MRM Health added: "*The consistency in clinical endpoints improved by MH002 in two clinical studies with different patient populations highlights the potential of MH002's mechanism of action, and its combined effect on mucosal healing and reduction of inflammation is promising, along with a very favorable benefit/risk balance, pending larger confirmatory studies.*"

Based on the combined results from both clinical trials and recent positive feedback from regulatory authorities, the Company is in the position to initiate Phase 2/3 development in Ulcerative Colitis, to be combined with further development in Pouchitis.

MH002 is currently the most advanced rationally designed live microbial consortium therapy in Inflammatory Bowel Diseases. It was developed through MRM Health's proprietary CORAL® Technology and comprises six well-characterized and safe commensal strains, selected and optimized to tackle key disease-driving mechanisms with enhanced potency, resiliency, and engraftment. MRM Health's breakthrough scalable and standardized cGMP manufacturing platform, allows for the manufacturing of complete consortia as a single drug substance. This ability of CORAL® to enable scalable, cost-effective manufacturing of complete optimized consortia in a single process is expected to provide both key regulatory and patient compliance advantages.

Sam Possemiers, Chief Executive Officer at MRM Health, said: *"These new clinical data further validate our proprietary CORAL® technology and reinforce the potential of MH002 as a novel and differentiated therapy for the treatment of diseases characterized by mucosal impairment and inflammation, both within IBD and beyond. These data enable us to advance to pivotal clinical development with MH002 later this year, and we are engaging with regulatory agencies in the US and EU to outline an accelerated Phase 2/3 development strategy*."

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About MRM Health

MRM Health is a clinical-stage biotech developing innovative therapeutics for inflammatory, CNS and metabolic diseases. The Company's most advanced program MH002 is in preparation for pivotal clinical development in Ulcerative Colitis and/or in the orphan disease indication Pouchitis. MRM Health leverages its proprietary disruptive CORAL® technology platform to design microbiome-based biotherapeutics, based on disease-focused specific combinations of 5 to 10 live gut bacteria, and to optimize them for faster onset-of-action and increased potency and robustness. A significant differentiator is the ability to manufacture these consortia as single drug substance in a single standardized, scalable and highly cost-effective process. In addition to the program in Inflammatory Bowel Diseases, MRM Health has ongoing preclinical programs in Parkinson's Disease and Spondyloarthritis, and partnered programs with IFF in Type 2 Diabetes and NAFLD.

For more information, please visit the website at www.mrmhealth.com.

About Pouchitis

Pouchitis (PC), an orphan disease indication within the Inflammatory Bowel Diseases (IBD), is the most prominent complication after surgical removal of the large bowel (colectomy) that is performed as a last resort treatment in Ulcerative Colitis (UC). PC is characterized by inflammation of the surgically constructed pouch after colectomy. Today, still 10 to 15% of all UC patients, having severe and/or treatment resistant disease, eventually require colectomy and pouch surgery. While temporarily improving their condition, PC however occurs in up to 50% of these patients within 1-2 years after surgery. Symptoms much resemble those of the UC they suffered from initially, i.e. debilitating diarrhea, abdominal pain, urgency, and rectal bleeding with significant impact on quality of life. Disease mechanisms include impaired gut wall barrier function linked to gut microbiome dysbiosis, translocation of microbial products and resulting immune cell activation, leading to chronic inflammation in the gut wall. Current treatment consists of antibiotics and in non-responders (when chronic and antibiotic resistant), mesalamine, corticosteroid or biological treatment may be prescribed. MH002 is designed to enrich the gut microbiome of UC patients and thereby tackle key disease-driving mechanisms considered root cause of the disease.

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