PRESS RELEASE

MRM Health Reports Positive Topline Results from Phase 2a Clinical Study with MH002 in Mild-to-Moderate Ulcerative Colitis

- Primary endpoint reached: safe and well tolerated, no evidence of adverse reactions related to MH002 when administered for 16 weeks
- Initial efficacy observed in clinically relevant parameters, including 17% significant improvement over placebo at week 8 in centrally-assessed Mayo Endoscopic Severity score (p=0.05) and significant improvement of stool consistency seen as from 2 weeks of treatment (p=0.006)
- At a mechanistic level, anti-inflammatory effects demonstrated by 42% decrease in median fecal calprotectin (a bowel inflammation marker) relative to placebo (18%)
- Full analysis and presentation of the data by end 2023; Progression to Phase 2/3 development initiated
- MH002 is currently the most advanced rationally-designed microbiome consortium therapy in the UC field

GHENT, Belgium, September 19, 2023 – **MRM Health NV, a clinical-stage biopharmaceutical company focused on developing next-generation live microbiome consortia therapeutics, today reports positive topline results from its Phase 2a clinical trial with MH002 in mild-to-moderate Ulcerative Colitis (UC).**

MRM Health's MH002-UC-201 study was a multi-center, double-blind, randomized, placebo-controlled trial in 45 UC patients at multiple clinical sites in Belgium, Poland and Czech Republic. The study was designed to evaluate safety (primary endpoint), initial efficacy and mechanistic effects of MH002 over eight weeks, with a further eight-week extension period. More information about the trial is available at clinicaltrialsregister.eu.

The primary endpoint was met with an excellent safety profile and tolerance at a fixed dose of 400mg per day over 16 weeks administration. Treatment-Emergent Adverse Events (TEAE) were reported in 35% of patients allocated to MH002 treatment compared to 57% when treated with placebo and there was no evidence of adverse reactions related to MH002.

Initial efficacy on disease activity was evidenced in clinically relevant parameters, including a 12% improvement in Mayo Endoscopic Severity (MES) score (p=0.05, 1-sided Wilcoxon rank sum test), while placebo worsened by 5%. Stool consistency significantly improved in the MH002 treatment group as from week 2 (p=0.006; 1-sided Student t-test). At the end of the eight-week period, 18% of subjects achieved clinical remission compared to 0% of the placebo group (Per-protocol analysis). As opposed to previous trials with other live biotherapeutics in UC, this study was performed successfully without vancomycin preconditioning.

At a mechanistic level, anti-inflammatory effect was demonstrated with 42% decrease in median fecal calprotectin (a clinically relevant bowel inflammation marker) compared to 18% in placebo at week 8.

"*These early results indicate that MH002 is safe and well tolerated by patients, and has potential efficacy in mild-to-moderate UC patients who have not responded sufficiently to first-line treatment*," **commented Séverine Vermeire, coordinating investigator of study MH002-UC-201 and Professor of Medicine at the KU Leuven, Belgium.** *"There is a significant absence of treatments for UC patients, particularly in this population, so I look forward to conducting the full analysis of the data and following MH002's progression through the clinic."*

Bruce Sands, Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York and paid consultant to MRM Health, **added**: "*MH002's mechanism of action and anti-inflammatory effect in UC look very promising, with the potential of a highly favorable benefit/risk balance, pending larger confirmatory studies. These topline results also suggest that this formulation could have applications across a wider range of other inflammatory bowel disorders, including pouchitis, in which MH002 is also being tested.*"

Full analysis and presentation of the data is expected by the end of 2023. The Company has initiated to progress the program into Phase 2/3 development.

Ludo Haazen, Chief Medical Officer at MRM Health, added: *"This first clinical study enables us to move forward with our clinical programme in UC. We are excited to see that MH002 differentiated in this early study significantly and consistently from placebo in clinically relevant parameters, including the centrally assessed MES, which was supported by the mechanistic parameters we have measured."*

MH002 is currently the most advanced rationally-designed consortium therapy in the UC field. It was developed through MRM Health's proprietary CORAL® Technology and comprises six well-characterized commensal strains, selected and optimized to tackle key disease-driving mechanisms with enhanced potency, resiliency, and engraftment. Production is via MRM Health's breakthrough scalable and standardized cGMP manufacturing platform, allowing the manufacturing of complete consortia as a single drug substance. The 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.

In addition to the recently completed UC trial, MH002 is being tested in an ongoing multi-center, open label Phase 2 study enrolling patients with acute Pouchitis, a rare disease with high unmet medical need.

Sam Possemiers, Chief Executive Officer at MRM Health, said: *"These early clinical data are very important for the Company, since they further validate our proprietary CORAL® technology which underlies our portfolio of live biotherapeutic products. The data enables us to take the next steps in our business strategy where we will be engaging with regulatory agencies in all territories and potential new partners as well as driving forward the rest of our development portfolio*."

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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, upon obtaining positive clinical results in a phase 2a clinical trial, and is being evaluated 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 IBD and UC

Ulcerative colitis (UC) is a chronic, autoimmune, inflammatory bowel disease (IBD) characterized by mucosal inflammation of the colon resulting in debilitating diarrhea, abdominal pain, and rectal bleeding with significant impact on quality of life of patients and an increased risk of colorectal cancer development. Whereas many treatments exist and are in development for moderate-to-severe UC, only very limited options are available for mild-to-moderate disease. Current therapies have a merely symptomatic anti-inflammatory and/or an immunosuppressant effect and in many cases fail to induce enduring remission and/or cause potentially severe adverse events. These treatments also do not tackle what is considered as one of the core problems of UC, the overall poverty of microorganisms present in the gut of UC patients, also termed gut dysbiosis. MH002 is designed to enrich the gut microbiome of UC patients and thereby tackle what is considered a root cause of the disease.

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