



PRESS RELEASE



MRM Health Announces First Patient Dosed with Next Generation Live Microbiome Consortia Therapeutic MH002 in Phase 1b/2a Study in Patients with Ulcerative Colitis

GHENT, Belgium, December 8, 2021 – **MRM Health, a clinical-stage biopharmaceutical company developing next-generation live microbiome consortia therapeutics, announced that the first patient received MH002 in a phase 1b/2a multi-center clinical trial in mild-to-moderate Ulcerative Colitis. MH002 is MRM Health's first clinical product candidate resulting from its proprietary and unique CORAL™ platform technology.**

"We are very excited about this next step in the development of MH002 in Ulcerative Colitis," said Sam Possemiers, Ph.D., Chief Executive Officer of MRM Health. "Treatment of the first patient in this study is a major achievement for our team, a milestone for the company, and an important step towards improving the lives of patients with Ulcerative Colitis (UC). We thank our Belgian and international investigators for their commitment in successfully advancing our first clinical program resulting from the CORAL™ platform."

MRM Health's MH002-UC-201 study is a multi-center, double-blind, randomized, placebo-controlled trial in multiple clinical sites in Belgium, Poland and Czech Republic and will enrol 45 mild-to-moderate UC patients. The trial will evaluate safety, mechanistic effects, and initial efficacy of MH002 on disease activity. More information about the trial is available at [clinicaltrialsregister.eu, with identifier 2020-004355-33](https://clinicaltrialsregister.eu/ct/ShowRecruit.aspx?Recruit=Identifier&Identifier=2020-004355-33).

"My medical team is very motivated to study this promising novel treatment in our patients," said investigator Prof. Pieter Dewint, (MD, PhD), Gastroenterologist at AZ Maria Middelares, Ghent, Belgium. "The potential to offer an effective treatment to our patients that is devoid of severe or serious risks would represent a true advancement for their well-being."

"There is an important medical need for an effective and safe new medicinal product for the treatment of mild-to-moderate UC," said Prof. Séverine Vermeire (MD, PhD), IBD expert at the Gastroenterology Department of the University Hospitals Leuven, Belgium, and principal investigator of the trial. "MH002 has all the characteristics and potential to fill that need and may become a novel tool in the first-line treatment of UC."

MH002 is the first product candidate resulting from MRM Heath's CORAL™ platform, in which key disease-driving mechanisms guide therapeutic microbial strain selection, to enter clinical studies in patients. Preclinical studies in inflammatory bowel disease (IBD) models showed that MH002 repairs gut microbiome dysbiosis, heals the dysfunctional intestinal barrier, and restores immune homeostasis with its differentiated mechanism targeting multiple key disease pathways. MH002 has demonstrated excellent safety and superior preclinical efficacy as compared to conventional, non-optimized microbiome therapeutics, as well as mesalamine, the current first-line standard of care in UC.

As part of the CORAL™ platform, MH002 is produced through a breakthrough scalable, robust, and standardized cGMP manufacturing technology, overcoming past microbiome challenges in manufacturing multi-strain consortia of uniform composition. CORAL™ allows the manufacturing of complete consortia as a single drug substance, expected to provide both key regulatory and patient compliance advantages.



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About MRM Health

MRM Health NV, Ghent, Belgium, is a biopharmaceutical company focused on the development of next-generation optimized consortium therapeutics based on the human microbiome. The company has built a diversified pipeline with its proprietary CORAL™ platform to design, optimize, and manufacture bacterial consortia as single drug substance. Its most advanced program MH002 is an optimized consortium of 6 rationally-selected and well-characterized commensal strains. MH002 is entering a Phase 1b/2a study in patients with mild-to-moderate ulcerative colitis in Q4 2021. Additional pipeline development includes a preclinical program in Parkinson's disease, two preclinical programs in metabolic disease (partnered with IFF Nutrition Biosciences, previously DuPont), and a discovery program in autoimmune disease, including spondyloarthritis.

About CORAL™

MRM Health's differentiating CORAL™ platform utilizes a bioinformatics-guided in-human discovery engine combined with a breakthrough in optimization and manufacturing of consortia as single drug substance. The proprietary consortia optimization technology allows to develop next-generation consortia therapeutics with faster onset-of-action and increased potency and robustness. The breakthrough scalable, robust, and standardized cGMP-compliant consortia manufacturing technology allows to manufacture complete therapeutic consortia as a single drug substance in a single manufacturing process which strongly surpasses existing approaches in speed, reduced complexity, increased robustness and lower cost.

About IBD and UC

Ulcerative colitis (UC) is a chronic, autoimmune, inflammatory bowel disease (IBD) characterized by mucosal inflammation of the rectum and colon resulting in debilitating diarrhea, abdominal pain, and rectal bleeding. Current treatments include symptomatic anti-inflammatory therapies and immunosuppressants. In many cases, these therapies fail to induce enduring remission and/or cause potentially severe adverse events.

Substantial clinical unmet need persists in UC as many patients remain refractory to standard of care and current treatments (e.g., anti-inflammatory, immunosuppression approaches) primarily provide symptomatic relief. MH002's disease-modifying mechanism is anticipated to induce remission via immunomodulation, rather than immunosuppression, resulting in superior safety with no elevated risks associated with reduced immune system functioning.

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