



MRM Health Receives CTA Approval for Phase 1b/2a Trial with Next Generation Optimized Consortium Therapeutic MH002 in Ulcerative Colitis

GHENT, Belgium, September 28, 2021 – **MRM Health, a biopharmaceutical company developing next-generation live microbiome consortia therapeutics, announced today that they have received regulatory approval from the Federal Agency for Medicines and Health Products (FAMHP) in Belgium to start a Phase 1b/2a trial with the novel next-generation optimized consortium therapy, MH002, in patients with mild-to-moderate ulcerative colitis (UC).**

MH002 is the first rationally-designed consortium therapy, in which key disease-driving mechanisms guide therapeutic microbial strain selection, to enter clinical studies in patients. Developed through MRM Health's proprietary Microbiome Optimization Technology, MH002 consists of 6 well-characterized commensal strains that are optimized to form a synergistic microecosystem driving differentiated potency, resiliency, and engraftment. Combining rational selection of disease-modifying strains with consortium optimization to ensure live delivery, engraftment, and durability is expected to result in greater efficacy than conventional microbiome therapeutics.

MH002 is produced using MRM Health's breakthrough scalable, robust, and standardized cGMP manufacturing platform, overcoming past microbiome challenges in manufacturing multi-strain consortia of uniform composition. MRM Health's standardized platform allows the manufacturing of complete consortia as a single drug substance, expected to provide both key regulatory and patient compliance advantages.

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.

MRM Health's Phase 1b/2a study is a multi-center, double-blind, randomized, placebo-controlled trial which will enroll 45 mild-to-moderate UC patients. The trial is designed to evaluate safety, mechanistic effects, and initial efficacy of MH002 on disease activity (EUDRACT Number: 2020-004355-33).

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.

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

"Reaching this milestone is the start of an exciting period of clinical development that is expected to provide the first clinical Proof-of-Concept of our differentiating consortia optimization platform and breakthrough single-process manufacturing technology," said Sam Possemiers (PhD), Chief Executive Officer and Co-Founder of MRM Health. "We are eager to work with our investigators to bring this first-in-class, rationally-designed bacterial consortia therapeutic product into patients."



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 platform to design, optimize, and manufacture bacterial consortia as single drug substances. 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 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.

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