PRESS RELEASE

MRM Health Starts Clinical Trial with Next-Generation Optimized Consortium Therapeutic MH002 in Pouchitis

GHENT, Belgium, June 28, 2022 – **MRM Health, a clinical-stage 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 2 trial with the novel next-generation optimized consortium therapy, MH002, in patients with Pouchitis.**

MH002 is the first, rationally designed, consortium therapy, in which key disease-driving mechanisms guide therapeutic microbial strain selection, to enter clinical development in Pouchitis. Pouchitis (inflammation of the surgically constructed pouch after colectomy) 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). Pouchitis occurs in up to 50% of these patients within 1-2 years after surgery. 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. To date, no registered oral therapeutics are available for Pouchitis, resulting in a significant unmet need for patients suffering from this highly debilitating, yet understudied rare disease indication.

Developed through MRM Health's proprietary CORAL® 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. The standardized CORAL® 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 has an excellent safety profile, repairs gut microbiome dysbiosis, heals the dysfunctional intestinal barrier, and restores immune homeostasis with its differentiated mechanism targeting multiple key disease pathways. MH002 is currently assessed in a Phase 1b/2a study in patients with mild-to-moderate UC. The product's disease-modifying mechanism is anticipated to induce remission in IBD via immunomodulation, rather than immunosuppression, resulting in superior safety with no elevated risks associated with reduced immune system functioning.

MRM Health's Phase 2 study in Pouchitis is a multi-center, open label trial which will enrol up to 20 acute Pouchitis patients. The trial is designed to evaluate safety, mechanistic effects, and efficacy of MH002 on disease activity (EUDRACT Number: 2021-006656-14).

"With no registered oral treatment available for Pouchitis, a strong medical need exists for an effective and safe new medicinal product for the treatment of this serious disease. With its differentiating mode-of-action, MH002 has a high potential to fill that need and may become a novel tool in the first-line treatment of Pouchitis," said Prof. Séverine Vermeire (MD, PhD), IBD expert at the Gastroenterology Department of the University Hospitals Leuven, Belgium, and coordinating investigator of the trial.

"This approval is another major step forward for MRM Health, as it allows to initiate a second clinical program and to further develop our rationally designed bacterial consortia therapeutic MH002 towards patients with IBD and beyond," said Sam Possemiers (PhD), CEO and Co-Founder of MRM Health.

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 currently being studied in two Phase 1b/2a studies in patients with mild-to-moderate Ulcerative Colitis and acute Pouchitis, respectively. Additional pipeline development includes a preclinical program in Parkinson's disease, preclinical programs in Type 2 Diabetes and in NAFLD (both 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.

For further information please contact:

Dr Sam Possemiers – CEO
Christiane Verhaegen – CFO
Phone: +32.9.277.08.50
info@mrmhealth.com

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