



## MRM Health Completes Patient Recruitment in Ulcerative Colitis Study, Secures Financing and Provides Outlook for 2023

- Completed patient enrollment in its phase 2a trial in Ulcerative Colitis with next-generation live microbiome consortia therapeutic MH002, with topline results expected in Q3 2023
- Has ongoing patient enrollment in its open-label phase 2 trial in the rare disease indication Acute Pouchitis.
- Attracted SFPIM, the Belgian Sovereign Wealth Fund, as new investor and obtained additional financing from existing investors and SFPIM to extend the company's runway and further build the clinical and preclinical pipeline.
- Achieved a next milestone payment from IFF upon achieving preclinical development targets within its partnered program in Type 2 Diabetes.
- Was awarded a 2M EUR subsidy grant from the Flemish subsidy agency VLAIO to further accelerate its preclinical program in Parkinson's Disease.
- Obtained 3 additional granted US patents and filed 2 novel international patent applications to further strengthen its IP portfolio.

GHENT, Belgium, March 7<sup>th</sup>, 2023 – **MRM Health—a clinical-stage biopharmaceutical company focused on developing next-generation live microbiome consortia therapeutics based on its proprietary and unique CORAL<sup>®</sup> platform technology - today provided a business update on its different ongoing therapeutic programs and an outlook for 2023.**

Key anticipated milestones for 2023:

- Top-line data from Phase 2a trial with MH002 in Ulcerative Colitis in Q3 2023 and mechanistic readouts in Q4 2023
- Initial data from open label Phase 2 trial with MH002 in Acute Pouchitis in Q4 2023
- Preclinical proof-of-concept in Type 2 Diabetes program partnered with IFF
- Completion of in vivo disease model studies in Parkinson's Disease program

*"In 2022, we delivered not only on key milestones regarding the progress of our clinical programs, but also on key preclinical targets and we obtained additional dilutive and non-dilutive financing to continue our ambitious growth plans,"* said Sam Possemiers, Chief Executive Officer of MRM Health. *"2023 also started very promising as we reached a major milestone by completing early January patient recruitment in the Phase 2a study with MH002 in Ulcerative Colitis, while patient recruitment in our phase 2 study in Acute Pouchitis continues to progress. Leveraging on the power of our CORAL<sup>®</sup> platform and building further on the successes from 2022, our preclinical programs in Type 2 Diabetes (T2D), non-alcoholic fatty liver disease (NAFLD) and Parkinson's Disease will further advance, with preclinical proof-of-concept expected in 2023 for the T2D program. Our effective progress provided confidence to SFPIM to join MRM Health and to partner with our existing investors to close a follow-on financing to continue on our path to success."*

### Clinical Development with MH002 in Ulcerative Colitis and acute Pouchitis

MRM Health's MH002-UC-201 study is a multi-center, double-blind, randomized, placebo-controlled trial with clinical sites in Belgium, Poland and Czech Republic, designed to evaluate safety, mechanistic effects, and initial efficacy of MH002 on disease activity. MRM Health has now enrolled all 45 mild-to-moderate UC patients. More information about the trial is available at [clinicaltrialsregister.eu](https://clinicaltrialsregister.eu).



Dr. Ludo Haazen, Chief Medical Officer at MRM Health commented: *“We are very pleased to have completed the recruitment for this ground-breaking UC trial, which is a true milestone for MRM Health and the development of our lead product MH002. We now look forward to analysing the clinical outcome data during 2023.”*

MH002 is currently the most advanced rationally-designed consortium therapy in the UC field. Developed through MRM Health’s proprietary CORAL® Technology, MH002 consists of 6 well-characterized commensal strains, selected and optimized to tackle key disease-driving mechanisms with enhanced potency, resiliency, and engraftment. MH002 is produced using MRM Health’s breakthrough scalable and standardized cGMP manufacturing platform, allowing the manufacturing of complete consortia as a single drug substance, expected to provide both key regulatory and patient compliance advantages.

In addition, MH002 is currently also being investigated in an ongoing multi-center, open label Phase 2 study enrolling patients with Acute Pouchitis, a rare disease with high unmet medical need.

### **Partnered program with IFF in Metabolic Diseases**

MRM Health has an ongoing corporate partnership with IFF since 2020, aiming to tackle a range of metabolic diseases. In this research, the proprietary CORAL® platform and selected IFF strains are combined to develop novel therapeutics based on live bacterial strain combinations. As part of its ongoing program in T2D, MRM Health recently reached a next milestone upon successfully achieving preclinical development targets. Within the ongoing program in NAFLD, MRM Health and IFF continue to further build on promising lead consortia and preclinical results, showing that a nine-strain bacterial consortium delays NAFLD progression and liver fibrosis. Part of this work was recently published in [Biomedicines](#).

### **Preclinical programs**

MRM Health has an ongoing preclinical program in Parkinson’s Disease (PD), in which it leverages on its proprietary CORAL® technology for the accelerated development of therapeutic consortia targeting neuroinflammation and neuronal cell death, two hallmarks of PD. Based on recent findings on specific microbiome signatures in PD, obtained from extensive in-house PD patient cohort analysis, and *in vivo* disease model data showing the capacity of specific bacterial strains to impact the target disease mechanisms, MRM Health was recently awarded a 2M EUR subsidy grant from the Flemish subsidy agency VLAIO. This will further accelerate the Company’s R&D activities in the field of PD and allow to progress a novel and differentiating therapeutic strategy to the clinic.

MRM Health further has an ongoing discovery program in the field of Spondyloarthritis (SpA), leveraging on its partnership with VIB and the leading expertise of prof. Jeroen Raes (VIB – KU Leuven) and prof. Dirk Elewaut (VIB – UGent). In-depth analysis of microbiome shifts in SpA patients revealed specific and actionable microbiome signatures in SpA. A rationally designed therapeutic consortium candidate was recently tested in the TNFdeltaARE mouse model, showing significant protection from disease development.

### **Intellectual Property**

MRM Health’s IP position in the microbiome field was significantly strengthened, when the US Patent Office recently issued 3 novel US Patents, covering a broad range of consortia therapeutics and therapeutic methods for reducing gastrointestinal diseases. Novel applications were filed in the last 12 months on both MRM Health’s therapeutic consortia and aspects of the proprietary CORAL® platform while additional patents are expected to be granted in 2023.



PRESS RELEASE



### **About CORAL®**

MRM Health's 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 for the development of 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 and increased robustness.

### **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 2 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, previously DuPont), and a discovery program in autoimmune disease, including spondyloarthritis.

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