# **NEWS RELEASE**

FOR IMMEDIATE RELEASE

Wednesday, March 3, 2021



# MOUNTAIN VALLEY MD PROCEEDING WITH FDA 505(b)(2) PATHWAY APPLICATION FOR NOVEL IVECTOSOL™

And provides update on its BSL-4 and Dose Sparing Adjuvant Trials

TORONTO, ON – March 3, 2021 - Mountain Valley MD Holdings Inc. (the "Company" or "MVMD") (CSE: MVMD) (FRA:20MP) (OTCQB: MVMDF) is pleased to announce it has contracted Camargo Pharmaceutical Services, LLC ("Camargo") to provide regulatory consulting services to support MVMD's pursuit of U.S. Food and Drug Administration (FDA) approval of its novel Ivectosol™ rapid dissolve oral format.

Camargo is recognized as one of the most experienced global organizations who specialize in drug and combination device product development and approval utilizing the regulatory pathway provided for in Section 505(b)(2) of the US Federal Food, Drug, and Cosmetic Act. Over the last decade, Camargo has established a leading track record with 505(b)(2) investigational new drug ("IND") and new drug applications ("NDA" preparations and submissions, including participation in more than 1100 Agency meetings and more than 200 FDA NDA and ANDA (Abbreviated New Drug Applications) approvals.

"After successful pre-clinical studies of our novel solubilized Ivectosol™ sublingual in our pre-clinical trials, this is a critical next step in the approval process to support our human application objectives," stated Mike Farber, Director of Life Sciences at Mountain Valley MD. "Camargo will be a great partner to accelerate our efforts for the initial pre-IND presentation to the FDA outlining Ivermectin's prior usage history and extensive safety record for the FDA's assessment and approval pathway."

The 505(b)(2) new drug application is one of three U.S. Food and Drug Administration drug approval pathways and represents an appealing regulatory strategy by way of helping to avoid unnecessary duplication of studies already performed on a previously approved drug. The Company believes the 505(b)(2) pathway will result in a much less expensive and much faster route to approval, compared with a traditional development pathway, while creating a new, differentiated Ivermectin product with tremendous commercial value.

"Camargo is proud to partner with Mountain Valley MD to advance their novel solubilized Ivermectin sublingual wafer," said Catherine Gatza, PhD, Vice President, Regulatory and Strategy at Camargo. "This program delivers important advantages to the parasitic infection treatment landscape by providing an alternative dosage form."

As previously communicated, MVMD's solubility technology applied to the Ivermectin drug is the only form in the world that uses strictly excipients that are currently approved by the US Food and Drug Administration (FDA), making it a leading candidate for human injection and sublingual applications as well as significantly broader husbandry and companion animal treatments based on its low viscosity.

"The U.S. FDA approval would prove the efficacy and safety of MVMD's Ivectosol™ wafer at one of the highest standards in the world and would assist in facilitating greater access to key global markets in an accelerated capacity," stated Dennis Hancock, President & CEO of Mountain Valley MD. "The human approval pathway timed with our aggressive pursuit of husbandry applications, is core to making our Ivectosol™ products the number one commercial form of Ivermectin in the world."

The Company's previously completed pre-clinical trial work with a third-party Contract Research Organization tested the solubilized Ivermectin via both an intramuscular injection and applied to rapid dissolve oral format with the Company's patented Quicksome™ desiccated liposome technology compared to existing oral and subcutaneous injection solutions. The results demonstrated that the Company's patented Quicksol™ solubilized Ivermectin offered superior pharmacokinetic performance across every single measure conducted, with no adverse side effects using up to 1/8<sup>th</sup> of the Ivermectin drug — a critical component that enables applications to use less of the Ivermectin drug while driving faster viral clearance.

#### TRIAL UPDATES

*Ivectosol*™

The Company is also pleased to announce that it has successfully formulated its Ivectosol™ product and provided trial quantities to its Bio Safety Level 4 ("BSL-4") laboratory partner. The trials are immediately commencing as scheduled. As previously outlined, the study is designed to prove the superiority of the Company's solubilized Ivermectin technology versus commercially available oral form in speed and efficacy of COVID-19 viral clearance and will also include the more virulent B.1.351 South African COVID-19 variant.

Inactivated Polio Vaccine – Dose Sparing Adjuvant

Additionally, the dose sparing adjuvant formulation work for the Inactivated Polio Vaccine has been completed by MVMD and Tulane University School of Medicine has confirmed it will be commencing its trials the week of March 8, 2021.

"The team has done an amazing job working through these incredibly tight timelines to advance our science and prove the efficacy of our technology," stated Hancock. "I would also like to thank our research partners who have worked hard to ready their teams to meet our aggressive trial schedules."

## ABOUT CAMARGO PHARMACEUTICAL SERVICES, LLC

Camargo Pharmaceutical Services partners with emerging biopharma companies to address unmet medical needs in rare and complex areas by optimizing the path to patients. We challenge the conventional drug development process, applying a novel approach to increase efficiency, reduce overall costs, and deliver safe and effective treatment to the right patients.

For nearly 20 years, we have helped clients successfully position high-science, creatively bold strategies to regulators and accelerate development with confidence. With more than 20 Ph.Ds. and other experts who work in integrated, multidisciplinary project teams, we serve as committed advocates for your drug development program by utilizing our extensive experience with all relevant FDA divisions, and integrating our 4 areas of specialization—commercial assessment and opportunity selection; medical viability, safety, and efficacy management; scientific experience; and regulatory expertise.

Camargo's accomplishments include:

- 250+ FDA drug approvals
- 200+ nonclinical programs executed through Camargo Research Group
- Participation in 3-6 FDA meetings every month
- 98%+ FDA concurrence rate for fulfilling NDA requirements
- Unparalleled experience in multiple submissions to every division of FDA's Center for Drug Evaluation and Research (CDER); and FDA's Center for Biologics Evaluation and Research (CBER)
- Global reach of 35+ countries

For more information, please visit our website at www.camargopharma.com.

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#### ABOUT MOUNTAIN VALLEY MD HOLDINGS INC

Mountain Valley MD is building a world-class biotech and life sciences company organization centred around the implementation of its patented Quicksome™ oral drug formulation and delivery technologies and its Quicksol™ solubilization technology for macrocyclic lactones, to innovate industry leading products that are sought out globally.

MVMD's proposition for delivering Quicksome™ formulations that have rapid onset, high bioavailability, low variability and precision dosing is core to the Company's success across key health and wellness categories. Consistent with its vision towards "Helping People Live Their Best Life", MVMD applies its Quicksome™ and Quicksol™ technologies to its ground-breaking work for advanced delivery of vaccines and pharmaceutical drugs as well as the development of products for pain management, weight loss, energy, focus, sleep, anxiety, and more.

The Company's patented Quicksome™ desiccation technology utilizes advanced liposomes and other stabilizing molecules to encapsulate and formulate active ingredients into highly efficient product formats that are consumed orally. The result is a new

generation of product formulations that are capable of delivering vaccines, drugs and nutraceuticals into the body faster, with greater impact, efficiency and accuracy.

The Company's patented Quicksol™ solubilization technology covers all highly solubilized macrocyclic lactones (including the drugs Ivermectin and Selamectin). MVMD's solubility technology applied to the Ivermectin drug is the only form in the world that only uses excipients that are currently approved by the US Food and Drug Administration (FDA), making it a leading candidate for human injection and sublingual applications as well as significantly broader husbandry and companion animal treatments based on its low viscosity.

For more Company information and contact details, visit www.mountainvalleymd.com.

SOURCE: Mountain Valley MD Holdings Inc.

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

Certain statements contained in this news release may constitute forward-looking information. Forward-looking information is often, but not always, identified by the use of words such as "anticipate", "plan", "estimate", "expect", "may", "will", "intend", "should", and similar expressions. Forward-looking information involves known and unknown risks, uncertainties and other factors that may cause actual results or events to differ materially from those anticipated in such forward-looking information.

The Company's actual results could differ materially from those anticipated in this forward-looking information as a result of regulatory decisions, competitive factors in the industries in which the Company operates, prevailing economic conditions, and other factors, many of which are beyond the control of the Company.

The Company is making forward-looking statements, including but not limited to with respect to: the commencement, execution and completion of the 505(B)2 pathway process; the results and implications thereof; and the commencement of trials related to the dose sparing adjuvant formulation work for the Inactivated Polio Vaccine.

The Company believes that the expectations reflected in the forward-looking information are reasonable, but no assurance can be given that these expectations will prove to be correct and such forward-looking information should not be unduly relied upon. Any forward-looking information contained in this news release represents the Company's expectations as of the date hereof and is subject to change after such date. The Company disclaims any intention or obligation to update or revise any forward-looking information whether as a result of new information, future events or otherwise, except as required by applicable securities legislation.

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